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Ecological Risk Assessment in the Federal Government

Committee on Environment and Natural Resources of the National Science and Technology Council

May 1999

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Ecological Risk Assessment in the Federal Government

Committee on Environment and Natural Resources
National Science and Technology Council

The purpose of this report is to review the major uses of ecological risk assessment by Federal agencies and to provide case studies that illustrate established and potential applications of ecological risk assessment in the Federal Government. The report presents the established roles of ecological risk assessment in Federal decision making, highlights the ecological risk assessment framework and terminology for its application to the various topics discussed, and promotes the use of ecological risk assessment to address the wide array of environmental issues.

Executive Office of the President
National Science and Technology Council
Committee on Environment and Natural Resources
Washington, D. C.

May 1999

Dear Colleague,

We are pleased to provide a copy of the report "Ecological Risk Assessment in the Federal Government." Federal agencies face a major challenge in assessing and evaluating numerous and varied ecological problems, ranging from the potential impacts of climate change to loss of biodiversity, habitat destruction, and the effects of multiple chemicals on ecological systems. Federal agencies have different responsibilities for addressing these problems: some have regulatory functions, others serve as natural resource trustees, and some must address ecological risks associated with their own activities. These differing responsibilities highlight the need for flexible problem-solving approaches. Increasingly, ecological risk assessment is being suggested as a useful tool for helping poliymakers to address this wide array of ecological problems.

This report demonstrates the application of ecological risk assessment by Federal agencies to a wide array of environmental issues and illustrates how other types of ecological and scientific assessments might benefit through the use of ecological risk assessment approaches. Continued progress in environmental protection requires the application of sound science to support risk management and decision-making. This report indicates the utility of ecological risk assessment for linking scientific information with informed decision-making in the Federal government.

Sincerely,

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Key to Agency Abbreviations:

DoD: U.S. Department of Defense
DOE: U.S. Department of Energy
EPA: U.S. Environmental Protection Agency
NASA: National Aeronautics and Space Administration
NOAA: National Oceanic and Atmospheric Administration/U.S. Department of Commerce
USDA: U.S. Department of Agriculture
USFS: U.S. Forest Service/U.S. Department of Agriculture
USFWS: U.S. Fish and Wildlife Service/U.S. Department of the Interior
USGS: U.S. Geological Survey/U.S. Department of the Interior

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PREFACE

This report was prepared by an interagency work group under the auspices of the Committee on Environment and Natural Resources (CENR). CENR is charged with improving coordination among Federal agencies involved in environmental and natural resources research and development, establishing a strong link between science and policy, and developing a Federal environment and natural resources research and development strategy that responds to national and international issues. CENR is one of five committees under the National Science and Technology Council, which was established by President Clinton in November 1993 as a cabinet-level council to coordinate science, space, and technology policies across the Federal Government.

A key issue across the Federal Government is how to evaluate numerous and varied ecological problems, ranging from potential global climate change to loss of biodiversity, habitat destruction, and the effects of multiple chemicals on ecological systems. Numerous Federal agencies have different responsibilities for addressing these problems: Some have regulatory functions, others serve as natural resource trustees, and some must address ecological risks associated with their own activities. These differing responsibilities highlight the need for flexible problem-solving approaches. Increasingly, ecological risk assessment is being suggested as a way to address this wide array of ecological problems.

To explore the uses and applicability of ecological risk assessment across the Federal Government, CENR sponsored workshops in October 1994 and December 1995 to promote information exchange. The development of this report was initiated as a follow-on to these workshops to review the major uses of ecological risk assessment by Federal agencies. This report provides examples of ecological risk assessments conducted in the Federal Government as well as ecological assessments that could benefit from ecological risk assessment methodologies. Recommendations for improving ecological risk assessment are made in the Executive Summary and at the end of each chapter. The authors would like to thank Michael Rodemeyer, Assistant Director, Environment, White House Office of Science and Technology Policy (OSTP); Fran Sharples, OSTP; and Jim Kariya, U.S. EPA; for their significant contributions to this document.

EXECUTIVE SUMMARY

Ecological risk assessment is a process for organizing and analyzing data, assumptions, and uncertainties to evaluate the likelihood of adverse ecological effects. The Committee on Environment and Natural Resources, Subcommittee on Risk Assessment, approved the formation of an ecological risk assessment work group to write a document to review the major uses of ecological risk assessment by Federal agencies. Eight task groups were formed with a total of 32 scientists from 9 Federal agencies. The task groups provided examples of current ecological risk assessment areas (established uses), potential uses where components of ecological risk assessment are used, and related ecological assessments and other scientific evaluations that might benefit from the use of ecological risk assessment methodologies. Established uses included the Toxic Substances Control Act (TSCA); the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); nonindigenous species; and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). Potential uses included agricultural ecosystems and endangered/threatened species. Related scientific assessments include oil spills (accidental releases), and ecosystem management. The work group members generally agreed that the U.S. Environmental Protection Agency's paradigm for ecological risk assessment and the associated terminology were a common scientific base from which to address the variety of uses of ecological risk assessment.

This publication demonstrates the broad applicability of ecological risk assessment as a flexible, problem-solving paradigm that can support environmental decision-making across the Federal Government. This document assists in communicating the process by which ecological risk assessments are performed to scientists and environmental policy makers with some technical expertise who are unfamiliar with ecological risk assessment. Communicating the process used for scientific risk assessments performed within the Federal sector is important for expanding the use of ecological risk assessment into areas where the potential benefits of such an approach have not yet been realized.

To enhance multiagency coordination, the following recommendations need to be addressed by the CENR agencies:

- Leverage technical advancements made in one area to fields where ecological risk assessment is less developed.
- Expand ongoing, multiagency dialogs between agencies and with outside researchers in order to develop procedures and tools (e.g., workshops, formation of ad hoc groups) for conducting ecological risk assessment and defining ecological criteria and indicators.

- Address nonindigenous species issues across agency boundaries to expand technical expertise, focus resources, and reduce redundancy. Promote regional and global management strategies to address nonindigenous species issues.

1. INTRODUCTION

The ecological problems facing environmental scientists and decision makers are numerous and varied. Growing concern over potential global climate change, loss of biodiversity, acid precipitation, habitat destruction, and the effects of multiple chemicals on ecological systems has highlighted the need for flexible problem-solving approaches that can link ecological measurements and data with the decision-making needs of environmental managers. Increasingly, ecological risk assessment is being suggested as a way to address this wide array of ecological problems.

Scientific publications and presentations at professional meetings on ecological risk assessment topics have greatly increased in the past few years. Various organizations have proposed standardized ecological risk assessment paradigms (e.g., U.S. EPA, 1998; NRC, 1993), and guidance on conducting ecological risk assessments has been or is being developed by national standardization organizations, States, Federal Government agencies, and other countries and international organizations. While these efforts have resulted in widespread agreement on the general ecological risk assessment process, there is still considerable variation in the way the process is applied in specific situations.

The objectives of this report are to provide examples of the existing uses of ecological risk assessment by Federal agencies as well as to illustrate how other types of ecological and scientific assessments used in the Federal Government might benefit through the use of ecological risk assessment approaches. The report highlights the use of ecological risk assessment to address a wide array of environmental issues. The intended audience for this document is scientists and environmental policy makers with some technical expertise who are unfamiliar with ecological risk assessment. Ecological risk assessors may find chapters of the document outside their area of expertise to be of interest.

This introductory section describes ecological risk assessment to those who may be unfamiliar with the process (1.1), and provides a case study overview (1.2).

1.1. ECOLOGICAL RISK ASSESSMENT

In this report, we use the ecological risk assessment process as described in the U.S. Environmental Protection Agency's (EPA's) recently published ecological risk assessment guidelines (U.S. EPA, 1998) as a benchmark for comparisons among the case studies. The guidelines were prepared by a panel of representatives from across EPA, organized by the Agency's Risk Assessment Forum. They are the product of nine years of development and peer review. Preliminary work on guidelines development began in 1989 and included a series of colloquia sponsored by EPA's Risk Assessment Forum to identify and discuss significant issues in ecological risk assessment. Based on this early work and on a consultation with EPA's Science Advisory Board (SAB), EPA decided to produce ecological risk guidance sequentially, beginning with basic terms and concepts and continuing with the development of source materials for the guidelines. The first product of this effort was the Risk Assessment Forum report, *Framework for Ecological Risk Assessment* (Framework Report; U.S. EPA, 1992), which proposed principles and terminology for the ecological risk assessment process. Since then, other materials were developed, including suggestions for guidelines structure, ecological assessment case studies, and a set of issue papers that highlighted important principles and approaches for EPA scientists to consider in preparing the guidelines. The final guidelines are a product of all these materials and were revised to reflect comments received from peer reviewers, the SAB, and the public.

Ecological Risk Assessment and Environmental Decision Making

Ecological risk assessment "is a useful risk management tool that:

! Highlights the greatest risks, which is helpful for allocating limited resources;
! Allows decision makers to ask 'what if' questions regarding the consequences of various potential management actions;
! Facilitates explicit identification of environmental values of concern; and
! Identifies critical knowledge gaps, thereby helping to prioritize future research needs" (SETAC, 1997).

While there are many different applications in which ecological risk assessments are used (e.g., regulation of hazardous waste sites, industrial chemicals, pesticides, or introduced species), more than the results of the risk assessment is needed to make environmental decisions. Some factors risk managers may consider in addition to the risk assessment include economics (e.g., the cost of various risk mitigation options), societal issues (e.g., public perceptions, environmental justice, or competing concerns such as any resulting loss of jobs), technology (e.g., treatment options, pollution prevention), or legal mandates.

Ecological risk assessment is a process for organizing and analyzing data, assumptions, and uncertainties to evaluate the likelihood of adverse ecological effects that may occur or are occurring as a result of exposure to one or more stressors. Stressors can be chemical, physical (e.g., habitat destruction), or biological (e.g., introduced species). Ecological risk assessment is helpful for environmental decision making because it provides risk managers with an approach to consider available scientific information along with other important factors to select a course of action. (Definitions of many of the terms used in this section are provided in Section 10, the glossary.)

Ecological risks are estimated by integrating exposure (the interaction of stressors and ecological receptors) and effects. All risk assessments involve some degree of uncertainty. Some elements of uncertainty can be reduced by gathering additional data; others cannot, such as the inherent variability in rainfall amounts or temperature fluctuations. Uncertainty analysis describes the degree of confidence in the assessment and can help risk managers focus future research on areas that will lead to the greatest reduction in uncertainty.

As shown in Figure 1-1, ecological risk assessment includes three primary phases: problem formulation, analysis, and risk characterization. Problem formulation is the initial phase of the process, which includes the development of assessment endpoints, conceptual models, and an analysis plan. Assessment endpoints are explicit expressions of the actual environmental value that is to be protected that link the risk assessment to management concerns. Assessment endpoints include both a valued ecological entity and an attribute of that entity that is important to protect and is potentially at risk (e.g., nesting and feeding success of piping plovers or areal extent and patch size of eelgrass). Potential interactions between assessment endpoints and stressors are explored by developing conceptual models that link anthropogenic activities with stressors and evaluate interrelationships among exposure pathways, ecological effects, and ecological receptors. The analysis plan justifies what will be done as well as what will not be done in the assessment, describes the data and measures to be used in the risk assessment, and indicates how risks will be characterized.

The analysis phase, which follows problem formulation, includes two principal activities: characterization of exposure and characterization of ecological effects. The process is flexible, and interaction between the ecological effects and exposure evaluations is critical. Both activities include an evaluation of available data for scientific credibility and relevance to assessment endpoints and the conceptual model. In exposure characterization, data analyses describe the source(s) of stressors, the distribution of stressors in the environment, and the contact or co-occurrence of stressors with ecological receptors. In ecological effects characterization, data analyses may evaluate stressor-response relationships or evidence that exposure to a stressor causes an observed response. The products of analysis are summary profiles that describe exposure and the stressor-response relationships.

Risk characterization is the final phase. During risk characterization, risks are estimated and interpreted and the strengths, limitations, assumptions, and major uncertainties are summarized. Risks are estimated by integrating exposure and stressor-response profiles using a wide range of techniques, such as comparisons of point estimates or distributions of exposure and effects data, process models, or empirical approaches such as field observational data.

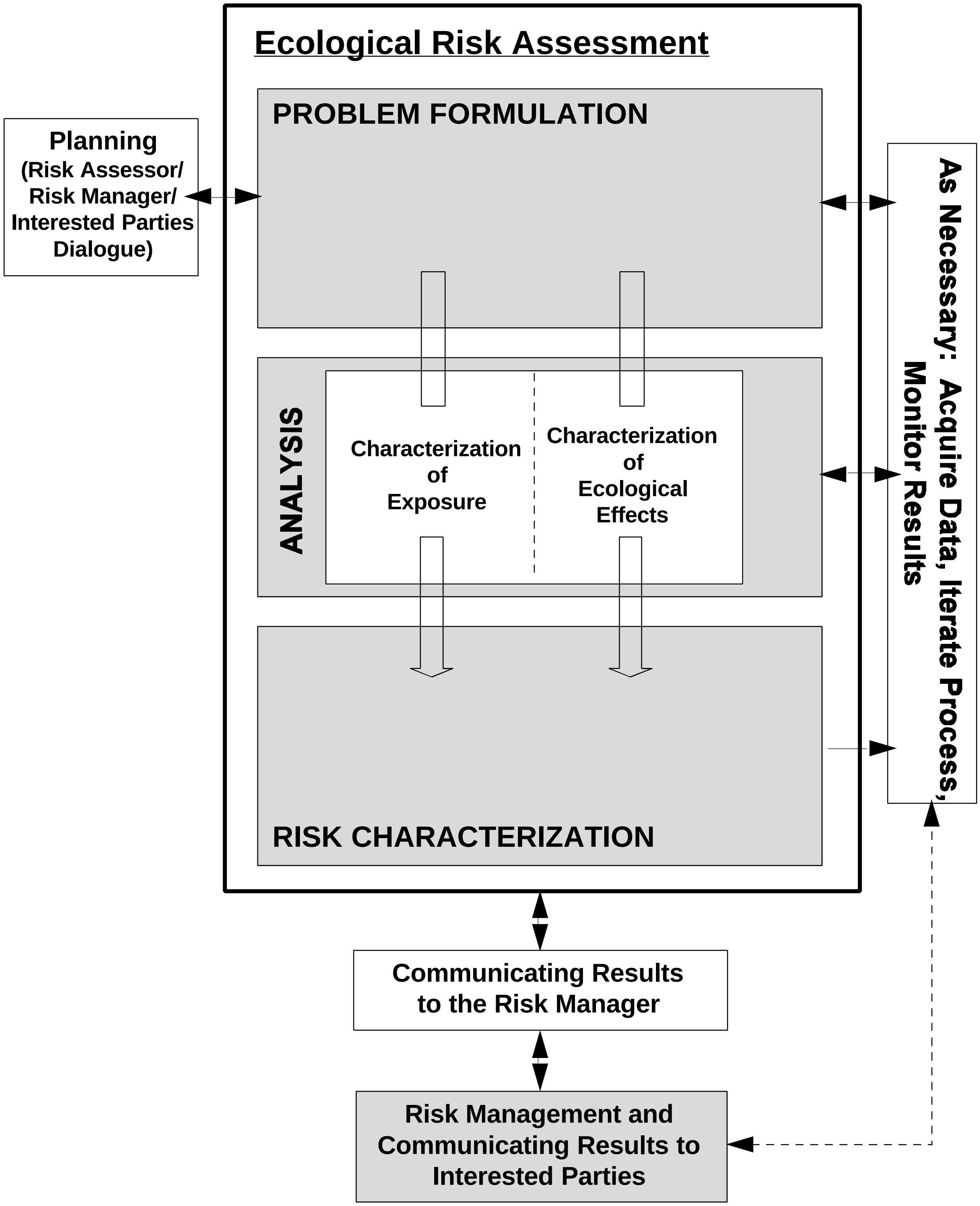

Figure 1-1. Framework for ecological risk assessment (U.S. EPA, 1998).

Risk assessors describe risks by evaluating the evidence supporting or refuting the risk estimate(s) and interpreting the adverse effects on the assessment endpoint. Criteria for evaluating adversity include the nature and intensity of effects, spatial and temporal scales, and the potential for recovery. Agreement among different lines of evidence of risk increases confidence in the conclusions of a risk assessment.

Several important activities are shown outside the risk assessment process in Figure 1-1, including discussions between risk assessors and risk managers. Interactions between risk assessors and risk managers at the beginning and end of the risk assessment are critical for ensuring that the results of the assessment can be used to support a management decision. Planning activities at the outset of a risk assessment foster agreements between risk assessors and risk managers concerning the management goals, risk assessment purpose, and resources available to conduct the assessment. Other interested parties also may be involved with planning (see text box). The box following risk characterization represents communication of the risk assessment results from assessors to managers.

The Role of Interested Parties in Planning

In some risk assessments, interested parties also take an active role in planning, particularly in goal development. Interested parties (commonly called "stakeholders") may include Federal, State, tribal, and municipal governments, industrial leaders, environmental groups, small-business owners, landowners, and other segments of society concerned about an environmental issue at hand or attempting to influence risk management decisions. The National Research Council describes participation by interested parties in risk assessment as an iterative process of "analysis" and "deliberation" (NRC, 1996). Interested parties may communicate their concerns to risk managers about the environment, economics, cultural changes, or other values potentially at risk from environmental management activities. Where they have the ability to increase or mitigate risk to ecological values of concern that are identified, interested parties may become part of the risk management team. However, involvement by interested parties is not always needed or appropriate. It depends on the purpose of the risk assessment, the regulatory requirements, and the characteristics of the management problem. When and how interested parties influence risk assessments and risk management are areas of current discussion (NRC, 1996).

The bar along the right side of Figure 1-1 highlights data acquisition, iteration, and monitoring. Monitoring data can provide important input to all phases of the risk assessment process. Monitoring data can also provide the impetus for a risk assessment by identifying changes in ecological condition, or can be used to evaluate risk assessment predictions, such as the success of mitigation or source reduction efforts or the extent and nature of any ecological recovery that may occur. The ecological risk assessment process is frequently iterative, and new data or information may require revisiting a part of the process or conducting a new assessment. Some assessments are designed in tiers, which are preplanned sets of assessments of progressive data and resource intensity. The outcome of each tier is either a management decision or the initiation of the next tier.

1.2. CASE STUDY OVERVIEW

To prepare this report, task groups of Federal scientists selected and identified case studies and other examples representing the diversity of ecological assessments commonly conducted in the Federal Government. The eight different types of assessments included in this report are summarized in Table 1-1. The assessments involve numerous Federal and State agencies as well as many nongovernmental organizations and were done in response to a range of statutory and nonstatutory requirements. Chemical, physical, and biological stressors were included in one or more of the assessments, as were a wide range of ecological systems.

The case studies are divided into three categories: established and potential applications of risk assessment and related scientific assessments. The established case studies follow most of the major elements of EPA’s ecological risk assessment guidelines (U.S. EPA, 1998), while the potential applications present varying degrees of implementation of ecological risk assessment, ranging from ecological assessments that could benefit from ecological risk assessment methods to those that have begun to apply the ecological risk assessment framework. Three cases in the established category are primarily concerned with chemical stressors (chemical premanufacturing notification, pesticide registration, and hazardous waste sites) and incorporate tiered assessments approaches that proceed from simple, relatively inexpensive assessments to more complex and costly assessments as necessary to provide a level of certainty sufficient to support a management decision. Initial screening assessments often involve using a hazard quotient, which is the ratio between an exposure concentration and an effects concentration. Quotients are most useful for categorizing risks as high or low.

Hazardous waste site assessments at U.S. Department of Energy facilities (Section 5) use the data quality objective (DQO) process in conjunction with ecological risk assessment. The DQO process is similar to the planning and problem formulation stages of an ecological risk assessment and emphasizes determining the boundaries of a study as well as evaluating the quality and quantity of the data necessary for the study. Another variation used at hazardous waste sites involves natural resource damage assessments, where emphasis is on demonstrating actual rather than potential ecological damage. In this case, ecological risk assessment is important for establishing a causal link between site contaminants and adverse effects.

Table 1-1. Case studies summary

Assessment type (report chapter)	Case study	Primary agencies involved[a]	Relevant legislation or program[b]	Spatial scale	Major stressor type(s)	Ecosystem type(s)[c]
Established uses of ecological risk assessment						
Ecological risks of a new industrial chemical under TSCA (Chapter 2)	New chemical	EPA	TSCA	National	Chemical	A/F
Ecological risk assessment under FIFRA (Chapter 3)	Synthetic pyrethroids	EPA	FIFRA	National	Chemical	A/F
Nonindigenous Species (Chapter 4)	Black carp	FWS		National	Biological	A/F
	Recombinant rhizobia	EPA	TSCA	Local		T
	Pine shoot beetle	USDA	PPA	Regional		T
CERCLA (Chapter 5)	Linden Chemicals and Plastics	EPA	CERCLA	Local	Chemical	W
	United Heckathorn					A/M
	Metal Bank of America	NOAA				A/F

Table 1-1. Case studies summary (continued)

Assessment type (report chapter)	Case study	Primary agencies involved[a]	Relevant legislation or program[b]	Spatial scale	Major stressor type(s)	Ecosystem type(s)[c]
Potential applications of ecological risk assessment[d]						
Agricultural ecosystems (Chapter 6)	Environmental Quality Incentives Program	USDA	FCIR-DARA, FAIR	National	Chemical, physical	A/F, T, W
	Conservative Research Progam		FSA			
	Ecological Impacts of Nonindigenous Shrimp Viruses	NOAA, EPA, USDA, FWS		Regional	Biological	A/M
Endangered/threatened species (Chapter 7)	Extinction models	FWS	ESA	Varies	Varies	Varies
Related scientific assessments						
Ecosystem management (Chapter 8)	Interior Columbia River Basin Scientific Assessment	USFS, BLM	NEPA	Regional	Physical, biological	A/F, T, W
	Southern Appalachian Assessment	12 Federal and 3 State agencies	NFMA		Physical, biological, chemical	A/F, T, W
	EPA watershed assessments (5)	Federal, State, NGOs	Multiple statutes			A/F, T, and/or W
Ecological risk assessment following the accidental release of chemicals (Chapter 9)	*Patricia Sheridan* release	Multiple agencies	CERCLA, FWCA, RAA, ESA, MBTA	Local	Chemical	A/F

[a]**Primary agencies involved:**
BLM: Bureau of Land Management
EPA: U.S. Environmental Protection Agency
FWS: U.S. Fish and Wildlife Service
NGO: Nongovernmental organizations
NOAA: National Oceanic and Atmospheric Administration

Table 1-1. Case studies summary (continued)

USDA:	U.S. Department of Agriculture
USFS:	U.S. Forest Service

[b]Legislation:

CERCLA:	Comprehensive Environmental Response, Compensation, and Liability Act
ESA:	Endangered Species Act
FAIR:	Federal Agriculture Improvement and Reform Act
FCIR/DARA:	Federal Crop Insurance Reform and Department of Agriculture Reorganization Act
FIFRA:	Federal Insecticide, Fungicide, and Rodenticide Act
FSA:	Food Security Act
FWCA:	Fish and Wildlife Coordination Act
MBTA:	Migratory Bird Treaty Act
NEPA:	National Environmental Policy Act
NFMA:	National Forest Management Act
PPA:	Plant Protection Act
RAA:	Refuge Administration Act
TSCA:	Toxic Substances Control Act

[c]Ecosystem type(s):

A/F:	Aquatic—freshwater
A/M:	Aquatic—marine or estuarine
T:	Terrestrial
W:	Wetlands

[d]Case studies included in this category are quite variable in their relationship to the ecological risk assessment process. Some are risk assessments, while others represent only a portion of the process.

Biological stressors, which include nonindigenous species that are introduced into an area, intentionally or unintentionally, are unique because of their ability to reproduce, adapt, and evolve (Section 4). The cases that focused on nonindigenous species introductions applied an approach consistent with ecological risk assessment. One unique aspect was the incorporation of some management considerations such as perceived impacts (social and political influences) into the risk assessment model. Although uncertainty in predicting risks associated with biological stressors can be very high, management decisions must be made, and it is important to convey these uncertainties to decision makers. As noted in Section 4, the strength of using risk assessment to evaluate nonindigenous species is that it provides a framework for taking the available information and placing it in a format that can be used and understood for making risk management decisions.

Sections 6 to 9 describe potential uses of ecological risk assessment and related scientific assessments. Applications include agricultural ecosystems, endangered/threatened species, ecosystem management, and oil spills. Many of the cases reported in these sections are not ecological risk assessments and use varying terminology and different approaches. However, as discussed below, many apply portions of the ecological risk assessment process and could potentially benefit from increased use of ecological risk assessment methods and approaches.

Ecosystem management is increasingly being used in assessments involving multiple stressors and multiple spatial and temporal scales. As described in Section 8.2.1.1, the Forest Service and Bureau of Land Management have developed a four-step framework for ecosystem management that includes monitoring, assessment, decision making, and implementation. While ecosystem management is not a form of ecological risk assessment, assessments done as a part of ecosystem management frequently share several common elements with ecological risk assessments. For example, both recognize the importance of preassessment planning, the need to link data gathering to assessment issues, and the importance of involving interested parties (stakeholders) in the process. The most direct attempt to incorporate ecological risk assessments in ecosystem management is illustrated by EPA's five watershed case studies (Section 8.2.3).

Ecosystem management frequently express its goals using terms such as *ecological sustainability*, *integrity*, or *health*. While these terms are useful as guiding principles, they must be explicitly interpreted to support an assessment. Some key questions (U.S. EPA, 1998) that need to be addressed include the following:

- What does sustainability or integrity or health mean for a particular system?
- What must be protected to meet these goals?
- Which ecological resources and processes are to be sustained and why?

- How will we know when we have achieved the goals?

Some believe that ecological risk assessment has only limited applicability to ecosystem management (Lackey, 1994). The perception is that ecological risk assessment is hampered by the difficulty in defining what constitutes adverse ecological effects in complex situations and that applying ecological risk assessments requires inappropriate simplifications to allow application of quantitative risk methods. In fact, ecological risk assessment is simply a tool for capturing scientific information and uncertainties in a way that can support decision making. Ecological risk assessment does not always use quantitative tools (e.g., see Section 4 on nonindigenous species), nor does it have to simplify information more than any other approach to a highly complex problem. Further, both ecosystem management and ecological risk assessment recognize the need for initial planning and discussions between risk assessors and risk managers (including stakeholders) to define management goals that reflect societal concerns and to communicate assessment results and decisions with the stakeholders, including the public. Difficulties in defining adverse ecological effects and resolving conflicting societal values are common to ecosystem management in general, not to any one type of decision support approach.

As with ecosystem management, application of ecological risk assessment to agricultural ecosystems has been varied in scope and extent. The shrimp virus case study (Section 6.2.2) illustrated a preliminary problem formulation relevant to on area of agricultural concern (aquaculture) that closely follows the ecological risk assessment process. Applying the process to the multiple stressors, multiple receptors, and larger geographic scales found in the Environmental Quality Incentives and Conservation Reserve Programs was more difficult. In these cases, the analysis focused heavily on the problem formulation phase, and quantitative analyses were not possible given the scope of the assessment and the limited resources available. The concept of assessment endpoints was modified slightly to accommodate program needs. Further adaption of the ecological risk assessment process to agricultural ecosystems is suggested, as are establishing an iterative process between risk assessors and risk managers, identifying when risk assessments are required, and clearly stating the risk management objectives.

The section on endangered species focuses on the use of specific modeling tools for estimating the risks of extinction of small populations. Some of the parameters in the models include characteristics that influence the probability of extinction (e.g., random demographic or environmental changes, loss of adaptive variation, environmental catastrophes, accumulation of deleterious genetic factors, or habitat fragmentation). This information could contribute to an ecological risk assessment that might also include considerations of exposure to anthropogenic stressors (e.g., habitat loss or introduced species), explicit descriptions of assessment endpoints and conceptual models, and a more complete risk characterization.

The last section of this report (accidental release of chemicals) is more typical of the established uses of ecological risk assessment for chemical stressors. What is different is the very short time frame required for decision making following a chemical spill. The ecological risk assessment process can be useful in helping to structure the problem-solving process and involving stakeholders, but ecological risk principles need to be incorporated in advance into the strategies that determine how an agency will respond to an accidental release. For example, area contingency plans could be restructured following ecological risk assessment principles.

Together, the established and potential uses of ecological risk assessment and related scientific assessments described in this report illustrate the broad usefulness of the ecological risk assessment process. The inherent flexibility of the paradigm provides the means to address a wide range of stressors, ecological systems, and biological, temporal, and spatial scales. Nevertheless, much remains to be done to further incorporate ecological risk assessment into the environmental decision-making process.

1.3. REFERENCES

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ESTABLISHED USES

2. ECOLOGICAL RISKS OF A NEW INDUSTRIAL CHEMICAL UNDER TSCA

2.1. SUMMARY

This chapter illustrates how useful ecological risk assessments can be conducted even when resources are severely constrained. EPA's Office of Pollution Prevention and Toxics (OPPT) conducts ecological risk assessments for new chemical substances regulated by the Toxic Substances Control Act (TSCA). Under TSCA, manufacturers and importers of new chemicals are required to submit a premanufacture notification (PMN) to EPA before they intend to begin manufacturing or importing. OPPT has only 90 days to complete the risk assessment and has very limited exposure and effects data. In addition, OPPT receives more than 2,000 PMN submissions every year, which limits the amount of resources available for each case.

For PMN evaluations, the ecological risk assessment process (problem formulation, analysis, and risk characterization) is applied in a tiered fashion. The initial planning and problem formulation stage is quite similar for most assessments, because the assessments are usually not site specific and similar models and endpoints are used for different chemicals. Assessment endpoints and measures of effect (measurement endpoints) are identified, and the analysis and risk characterization phases are conducted sequentially using additional data and fewer worst case assumptions with each successive tier. The overall approach is to compare potential ecological effect concentrations that have been adjusted for uncertainty with potential exposure concentrations. If a risk is ascertained, more detailed analyses are performed.

Because of the paucity of data, there is a heavy reliance on the use of structure-activity relationships (SARs) to predict ecotoxic effects and exposure/fate characteristics (such as physical/chemical properties and biodegradation), and uncertainty (assessment) factors are used to compensate for a lack of definitive data when comparing effects concentrations with exposure levels. Given the constraints on the assessments, it is not possible to quantify effects on the assessment endpoint: populations and communities of aquatic organisms and aquatic ecosystems. Nevertheless, the risk assessment approach provides a useful way of applying scientific information to environmental decisionmaking.

The case study in this chapter focuses on the assessment of a PMN substance, i.e., an alkylated diphenyl, that is a neutral organic compound. The PMN substance was likely to be discharged into freshwater aquatic systems, so the assessment focused on aquatic organisms (e.g., fish, aquatic invertebrates, and algae). Beginning with SAR toxicity predictions and simple dilution models for exposure, the risk assessment proceeded through five iterations. During risk characterization at the end of each iteration, a quotient method was used to compare exposure concentrations with the ecological effect concentrations. A ratio of 1 or greater indicated a potential risk. The first four iterations identified an ecological risk and resulted in the collection

of additional and more specific ecological effects test data and more detailed information on potential exposures to the PMN substance. The final outcome was that the PMN substance could be used only at specific sites because there was uncertainty as to whether the concern level (1 µg/L) might be exceeded at sites not identified and characterized by the submitter.

OPPT risk assessment results are used as the basis for any of several risk management options, including a variety of regulatory enforcement actions such as banning discharges to water or requiring pretreatment. This case study illustrates how an efficient and pragmatic ecological risk assessment process can assist in eliciting reasonable risk management decisions.

2.2. INTRODUCTION

The prospective evaluation (and risk assessment) of new industrial chemicals and the retrospective assessment of an inventory of existing chemicals are within the purview of EPA's Office of Pollution Prevention and Toxics (OPPT, formerly the Office of Toxic Substances). This office and its mission were established when the Toxic Substances Control Act (TSCA) was passed in 1976 to regulate the chemicals in commerce that were not covered by other legislation; that is, TSCA covers only industrial chemicals (e.g., solvents, polymers, adhesives, coatings, plastics, pigments, detergents) and not pesticides, pharmaceuticals, etc.

In 1979, almost 62,000 chemical substances were reported to be in commerce, and these were "grandfathered" as the TSCA inventory of existing industrial chemicals. Chemicals not in this inventory were to be considered new industrial chemicals, and more than 32,000 of these have been submitted by industry for assessment since July 1979. Via the inclusion of about 13,000 new industrial chemicals that have been assessed for risk and are now in commerce, the TSCA inventory has now increased to more than 75,000 chemical substances with a total production/import volume that was about 6 trillion lbs/year (2.7 trillion kg/year) in 1989 (INFORM, 1995). However, the total made and/or imported into the United States in 1989 was larger than this estimate; approximately 25,000 existing chemicals were not reported because they did not reach the 10,000 lbs/site/year reporting threshold or because they were inorganic chemicals. In addition, from 1989 through 1995, the production of just the top 50 organic and inorganic chemicals in the United States increased 33% and 15%, respectively (Zeeman, 1996).

2.2.1. EPA/OPPT Risk Assessment Approach

This overview is based on OPPT's ecological risk assessment of a new chemical premanufacture notification (PMN). The PMN case study (U.S. EPA, 1994) originally was prepared to illustrate the consistency between the OPPT ecological risk assessment approach and EPA's Framework for Ecological Risk Assessment (U.S. EPA, 1992) (Figure 2-1); that is, they are both composed of three phases: problem formulation, analysis, and risk characterization.

This framework approach and several other such case studies were then used as a basis for the development of, and are therefore consistent with, EPA's Guidelines for Ecological Risk Assessment (U.S. EPA, 1998). Portions of the OPPT/TSCA PMN case study were even used to illustrate certain features of ecological risk assessment in the guidelines report.

This OPPT approach to ecological risk assessment of new industrial chemicals has been in place for more than a decade (Zeeman and Gilford, 1993). The specific example presented here (Section 2.3) is abbreviated from the original PMN case study. The PMN case study also was used as the basis for a more comprehensive publication of OPPT's methods for ecological risk assessment in the peer-reviewed literature (Nabholz et al., 1998).

OPPT's overall approach to assessing the risks of new chemicals is to compare potential ecological effect concentrations that have been adjusted for uncertainty (i.e., concern concentrations) with potential exposure concentrations. The process often begins with predicting toxicity, adjusting these effect concentrations for uncertainty, and contrasting one or more of these concern concentrations with one or more predicted environmental concentrations from simple stream flow dilution models that typically result in reasonable worst-case exposure scenarios. If a risk is ascertained, more detailed analyses are performed (Figure 2-2). Because of the paucity of data typically associated with new chemical PMN submissions (see discussion in Section 2.2.2, Statutory and Regulatory Background), there is a heavy reliance on the use of quantitative structure-activity relationships (QSARs) to predict ecotoxic effects to develop a stressor-response profile or an ecotoxicity profile (Nabholz, 1991; Zeeman et al., 1993, 1995).

Figure 2-2 does not include all likely risk management options. In addition to obtaining additional exposure and ecological effects information, risk management options can include a variety of regulatory enforcement actions, such as requiring pretreatment or even banning discharges to water. In any event, OPPT risk assessors must ascertain that a risk exists before OPPT risk managers need to exercise these risk management options.

The approach taken in this PMN evaluation has the following strengths: (1) it relates measurement endpoints to an assessment endpoint; (2) it demonstrates that ecological risk assessments can be conducted with minimal toxicity data and exposure data; (3) it demonstrates the usefulness of SARs in establishing a toxicity or stressor-response profile; and (4) it demonstrates that regulatory decisions can be made quickly using only the best data available at the time.

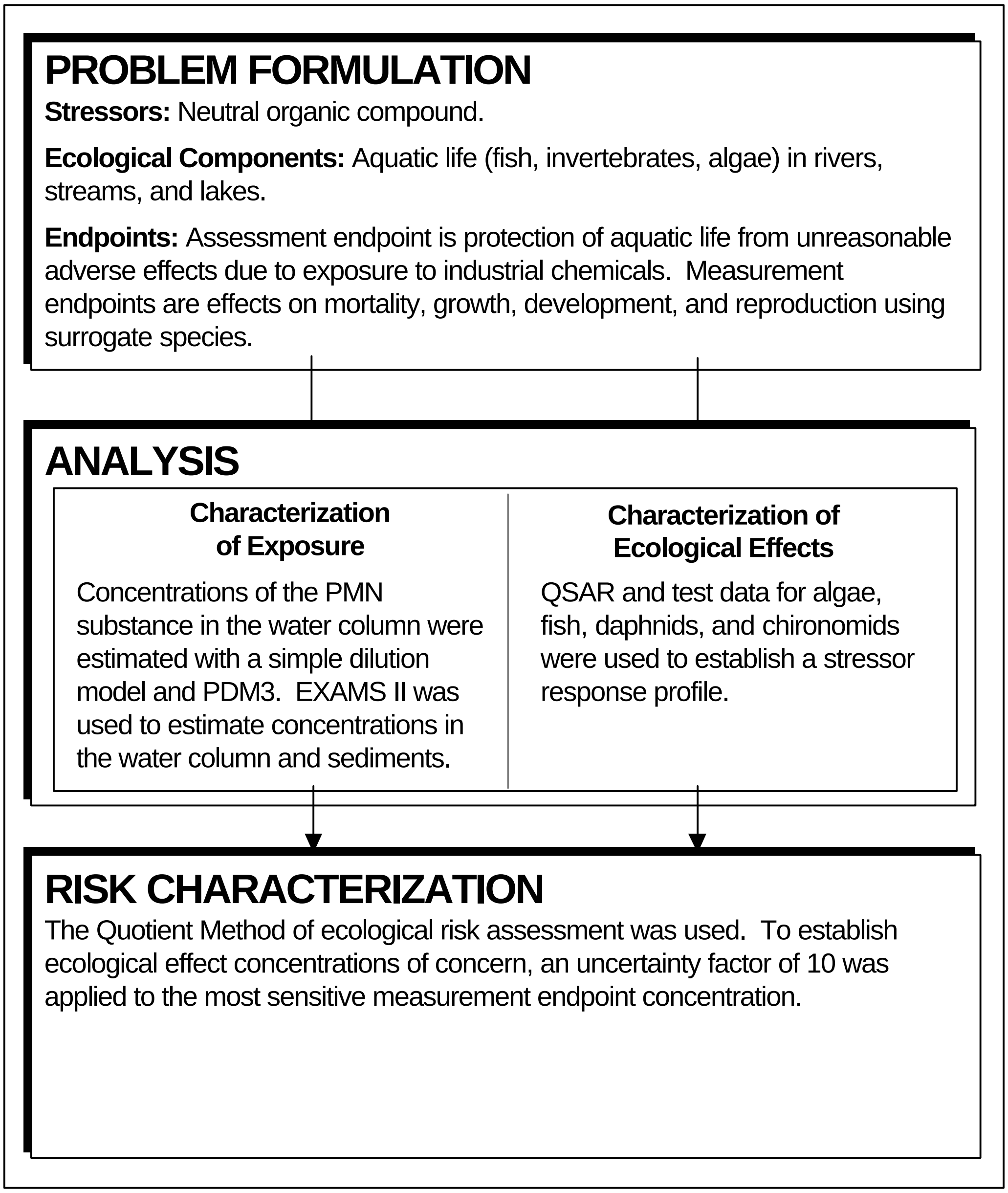

Figure 2-1. Structure of assessment for effects of a PMN substance.

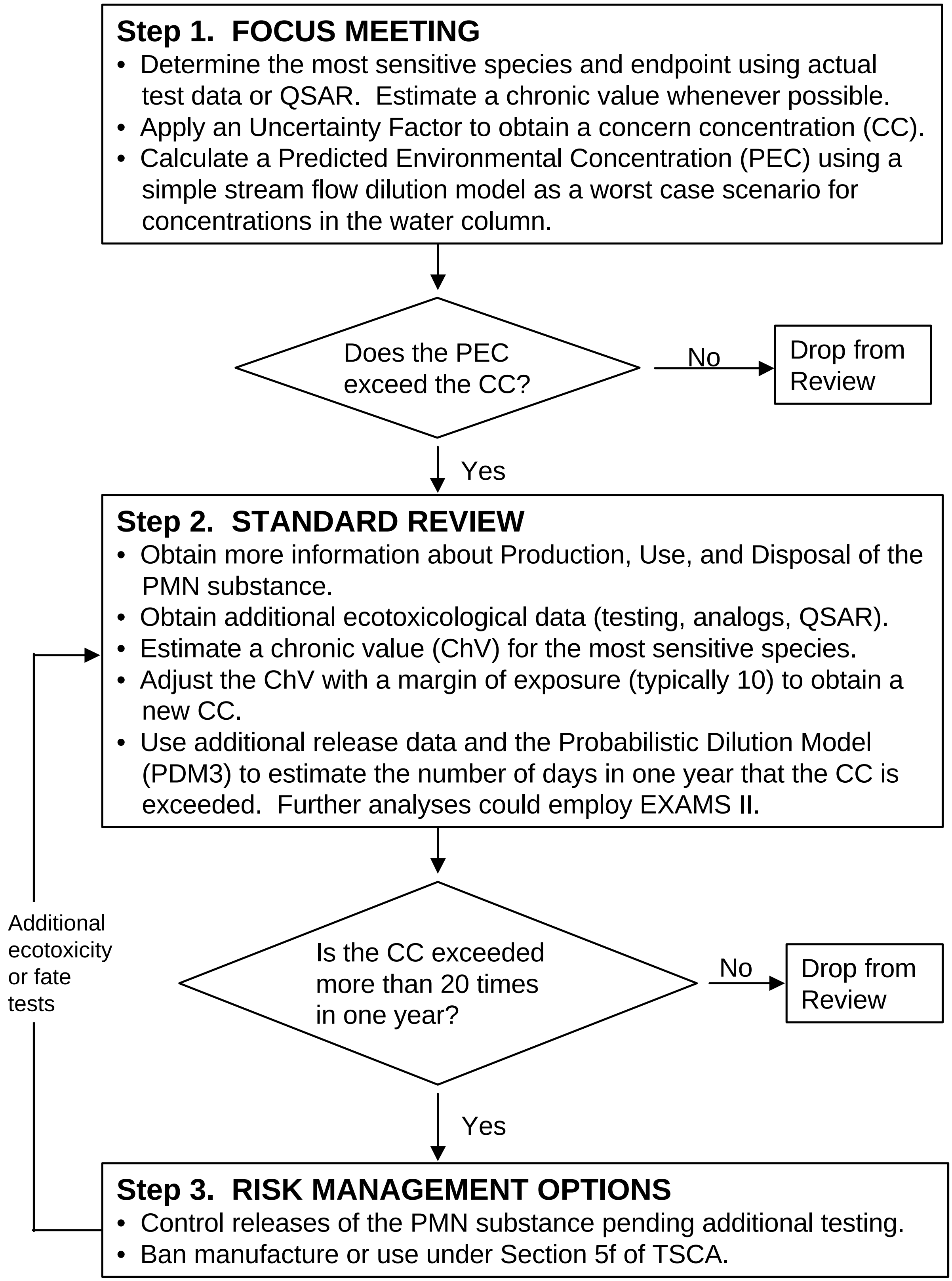

Figure 2-2. Flow chart and decision criteria for the ecological risk assessment of a PMN substance.

2.2.2. Statutory and Regulatory Background

TSCA provides for the regulation of chemicals not covered by other statutes (e.g., Food, Drug, and Cosmetic Act; Federal Insecticide, Fungicide, and Rodenticide Act). TSCA requires the assessment and, if necessary, regulation of all phases of the life cycle of industrial chemicals: manufacturing, processing, use, and disposal.

TSCA regulates two categories of industrial chemicals: (1) existing chemicals in commerce on the TSCA Chemical Substances Inventory, and (2) new chemicals that are not on this inventory. The inventory includes both chemicals in commercial production between 1975 and 1979 and the chemicals reviewed under the new chemical PMN program that went into commercial production after 1979. Section 5 of TSCA requires manufacturers and importers of new chemicals to submit a PMN to EPA before they intend to begin manufacturing or importing. EPA has up to 90 days to evaluate whether the substance will present an unreasonable risk of injury to human health or the environment. With good cause, EPA can allow an extension for another 90 days for the evaluation of the chemical.

In addition to the short review time allowed, three major difficulties are associated with evaluating PMNs. The first is the confidential business information (CBI) protection afforded by TSCA. Under this protection, manufacturers and importers can designate as CBI many characteristics of the PMN substance, such as chemical name, structure, intended uses, and sites of manufacture and use. This information is not available to the public, and only personnel with TSCA CBI security clearance and members of Congress can access the information. There are strict safeguards against disclosure of the CBI. The second difficulty is that, on average, manufacturers and importers currently submit more than 2,200 new chemical notices to EPA annually (Zeeman et al., 1995; Zeeman, 1997). The third difficulty is that only the following information must be submitted: chemical identity; molecular structure; trade name; production volume, use, and amount for each use; by-products and impurities; human exposure estimates; disposal methods; and any test data that the submitter may have. The manufacturer does not have to initiate any ecological or human health testing before submitting a PMN. Only about 5% of the PMNs reviewed to date contain ecological effects data, and most of those data consist of acute toxicity tests performed on fish (Nabholz, 1991; Nabholz et al., 1993a; Zeeman, 1995; Zeeman et al., 1993, 1995).

2.3. CASE STUDY: DESCRIPTION OF A NEW CHEMICAL ASSESSMENT UNDER TSCA

This case study describes how OPPT evaluates the ecological risks of a PMN substance. The risk assessment begins with a reasonable worst-case analysis using a stream flow dilution model to estimate environmental concentrations. This is the typical approach taken by OPPT, and it results in conservative estimates of aquatic exposures. OPPT risk assessors initially use any measured ecotoxicity data and SARs available to evaluate effect concentrations and dose-response curves for a new substance. The assessors then adjust these effect concentrations with assessment factors (or uncertainty factors) to set concern concentrations in the environment for the chemical. The quotient method is used to integrate these exposures and effects into a quantitative estimate of risk. That level of assessment typically suffices to show little or no risk for the majority of new chemicals assessed by OPPT.

Because the initial worst-case assessment identified a risk potential for this specific PMN chemical, additional iterative analyses were performed using actual test data and a more refined exposure analysis using a probabilistic dilution model (PDM3). The second risk characterization indicated risks to pelagic and benthic aquatic life; therefore, OPPT risk assessors used the exposure analysis modeling system (EXAMS) II model and generic site data to predict concentrations in both the water column and sediments. OPPT assessors estimated toxicity to benthic organisms using the chronic test data for fish and daphnids and assumed that the sediments would decrease toxicity through adsorption of the chemical to the organic matter in sediments. The results of these analyses still identified a potential risk.

The submitter then supplied OPPT with more precise data on the use and disposal of the PMN substance, that is, a list of specific use sites. OPPT assessors input data for each of these sites into EXAMS II and the results indicated little potential risk to benthic organisms at many of the identified sites. OPPT was ready to issue a consent order to restrict use of the PMN substance to the identified sites that posed low risk to the aquatic environment; however, the submitter chose to perform OPPT's recommended test with contaminated/spiked sediments using chironomids as the surrogate species for benthic organisms. The results of the test indicated moderate toxicity and little potential risk to benthic organisms at the identified sites after 1 year's release. The final outcome was that EPA restricted the use of the PMN substance to the identified sites because there was uncertainty as to whether the concern level of 1 µg/L might be exceeded at sites not identified and characterized by the submitter.

2.3.1. Background Information and Objective

OPPT performs the analyses listed below in assessing the human and ecological risks of PMN substances. For a more detailed discussion of the process, see U.S. EPA 1986, Auer et al., 1990; Moss et al., 1996; Nabholz, 1991; Nabholz et al., 1993a; and Wagner et al., 1995.

2.3.1.1. *Chemistry Report*

The Industrial Chemistry Branch of OPPT's Economics, Exposure, and Technology Division (EETD) evaluates PMNs to ensure that: (1) the chemical name matches the structure,

(2) the chemical/physical properties are accurate, (3) the information about the manufacture and processing is accurate, and (4) the uses are consistent with the chemical.

2.3.1.2. *Engineering Report*

The Chemical Engineering Branch of EETD estimates worker exposure during the life cycle of the chemical (manufacturing, processing, use, and disposal) and estimates releases of the chemical to the environment. The sites of release can be generic or specific using standard industrial codes.

2.3.1.3. *Exposure Assessment*

The Exposure Assessment Branch of EETD evaluates (1) available fate, transport, abiotic, and biotic fate parameters, and (2) consumer exposure. This is analogous to the exposure profile discussed in EPA's framework report (U.S. EPA, 1992) and the guidelines report (U.S. EPA, 1998). The exposure assessment estimates the environmental concentrations likely to occur during the life cycle of the PMN substance. This includes an evaluation of potential exposure from releases to surface waters, landfills, and land spray, as well as nonoccupational (consumer) exposures. Environmental concentrations can be generic or site specific. PMN substances frequently are discharged to water; therefore, more than 80% of PMN exposure assessments address aquatic environments, chiefly rivers and streams.

2.3.1.4. *Ecological Hazard Assessment*

Also known as a toxicity profile in OPPT, the ecological hazard assessment is analogous to the stressor-response profile discussed in the framework report (U.S. EPA, 1992) and guidelines report (U.S. EPA, 1998); this assessment was performed by the Environmental Effects Branch of the Health and Environmental Review Division (now the Risk Assessment Division). The initial ecological hazard assessment predicts and evaluates the potential adverse ecological effects of a PMN substance and relies primarily on SARs. For many classes of discrete organic chemicals reviewed by OPPT (about 50% of which are neutral organic chemicals), SARs are available that permit a prediction of acute and chronic toxicity to surrogate species, such as fish, aquatic invertebrates, and algae (Clements, 1988, 1994; Auer et al., 1990; Nabholz, 1991; Nabholz et al., 1993a, 1993b; Zeeman et al., 1993, 1995; Clements and Nabholz, 1994; Zeeman, 1995). The Risk Assessment Division also reviews the results of submitted test data and, if valid and adequate for risk assessment, incorporates them into the ecological hazard assessment.

2.3.1.5. *Ecological Risk Assessment*

In practice, staff of the Risk Assessment Division develop the ecological risk assessment for new chemicals and support them. Ecological risk assessments are conducted in a tiered fashion (see Figure 2-2). Initial hazard and exposure assessments are evaluated at the first risk assessment meeting, that is, FOCUS meeting, to ascertain if there are any potential risks. If risks are not identified at the FOCUS meeting, the chemical is typically dropped from further review. If a risk is identified, which happens about 5% of the time, the PMN substance undergoes a more detailed assessment, called a standard review (Wagner et al., 1995; Moss et al., 1996). Alternatively, additional information may be requested from the manufacturer or importer immediately following the FOCUS meeting. If a risk is still identified after all additional information has been submitted, then risk management options are considered. Possible risk management options include but are not limited to (1) control options (such as no releases to water) pending further tests of the PMN substance, (2) issuance of a TSCA significant new use rule, and (3) direct control under Section 5f (e.g., banning the manufacture or use of the PMN substance).

2.3.2. Problem Formulation

2.3.2.1. *Stressor Characteristics*

Table 2-1, which appears in Section 2.3.3.1.1, lists the physical/chemical properties of the subject PMN substance. The manufacturer declared the chemical identity, structure, intended uses, and sites of use as CBI. This particular example evaluated only the parent compound because OPPT risk assessors did not expect the PMN substance to readily degrade or be transformed into more toxic metabolites.

2.3.2.2. *Ecosystem Potentially at Risk*

The processing, use, and disposal sites were adjacent to rivers and streams. OPPT assessors expected the PMN substance to be discharged to such rivers and streams. Thus, pelagic and benthic aquatic populations and communities were determined to be potentially at risk.

2.3.2.3. *Ecological Effects*

The PMN substance was an alkylated diphenyl, and it belongs to a class of chemicals known as neutral organic compounds. These chemicals are nonelectrolyte and nonreactive and exert toxicity through a narcotic or nonspecific mode of action (Lipnick, 1985; Auer et al., 1990; Veith and Broderius, 1990). Neutral organic compounds can exert both acute and chronic effects. The toxicity of neutral organic compounds has been correlated with molecular weight and the logarithm of the K_{ow}. Experimental data have shown that neutral organics with a log K_{ow} of

5.0 or more do not exert pronounced acute effects (toxic effects such as mortality or immobilization within 2 to 4 days). This is due mainly to the low water solubility of such compounds, which results in decreased bioavailability to aquatic organisms. Because of this decreased bioavailability, exposure durations of 4 days or fewer are typically insufficient to elicit marked acute effects (e.g., as measured by a 96-h LC_{50} test). Because of the high K_{ow} of this PMN substance, OPPT risk assessors expected only chronic effects to be able to occur at or below the chemical's aqueous solubility limit.

OPPT typically assesses ecological effects for three trophic levels of food webs: primary producers (algae), primary consumers (aquatic invertebrates), and forage/predator fish. OPPT assessors use the most sensitive species and toxicological effect for the initial risk assessment. Unless only chronic effects are expected, such as for the PMN substance in this study, OPPT usually assesses both acute and chronic effects. The ecological effects characterization is based on effects on mortality, growth and development, and reproduction. The SARs used for neutral organic chemicals are:

Fish acute toxicity (Veith et al., 1983)
Daphnid acute toxicity (Hermens et al., 1984)
Green algal toxicity (Clements, 1988, 1994)
Fish chronic value (Broderius and Russom, 1989)
Daphnid chronic value (Hermens et al., 1984)
Green algal chronic value (Clements, 1988, 1994).

The rationale and approach used to assess these effects are presented under measurement endpoints (Section 2.3.2.5).

2.3.2.4. *Assessment Endpoints*

TSCA was intended to prevent unreasonable risks to health and the environment as a result of the manufacture, processing, use, and disposal of industrial chemicals. The assessment endpoint (Suter, 1990) used in this study was the protection of aquatic organisms (algae, aquatic invertebrates, and fish). OPPT assessors assumed that any effects from the PMN substance would be exhibited at least up to the population level of organization.

2.3.2.5. *Measurement Endpoints*

OPPT assessors used the following measurement endpoints (Suter, 1990) to assess the risks to the assessment endpoint:

- Mortality

- Growth and development
- Reproduction.

Clements (1983) and EPA (1983) present the rationale for selecting these endpoints. In summary, documented evidence indicates that xenobiotics can adversely affect these endpoints both directly and indirectly. Since populations are governed by mortality, growth and development, and reproduction, OPPT assessors presume that adverse effects to these measurement endpoints would manifest themselves at least up to the population level of ecological organization. Thus, there is a logical connection between the assessment endpoint (i.e., the protection of aquatic life, at least up to the population level) and the measurement endpoints.

OPPT uses a tiered approach when testing the toxicity of a given industrial chemical (U.S. EPA, 1983; Smrchek et al., 1993; Zeeman and Gilford, 1993). The first tier consists of relatively inexpensive short-term tests that measure acute effects chiefly on the three trophic levels discussed in Section 2.3.2.3, Ecological Effects, that is, mortality to fish and aquatic invertebrates and population growth for green algae. The first tier or "base set" for aquatic toxicity consists of a 96-h fish acute test, a 48-h daphnid test, and a 96-h algal test. Because the algal test represents exposure across about eight generations of algal cells, OPPT considers the algal test to be representative of chronic toxicity to algal populations.

Additional tiers consist of chronic tests, such as the fish early life-stage toxicity test, which measures effects on mortality and growth and development, and the daphnid chronic test, which measures effects on survival and reproduction. OPPT assessors typically must ascertain a potential risk before proceeding to request any acute or chronic toxicity testing. For high-K_{ow} chemicals, such as the subject PMN, OPPT assessors usually expect little or no acute toxicity to be seen from such short-duration tests, and most everyone agrees to save time and money by going directly to the tier of chronic toxicity testing.

2.3.2.6. *Conceptual Model*

On the basis of experience with neutral organic compounds and available SARs, it was clear that the high K_{ow} for the PMN substance indicated a risk of chronic toxicity only to pelagic and benthic aquatic organisms. Principal concerns were for effects on mortality, growth and development, and reproduction. OPPT assessors presumed that these effects would be manifested at least up to the population level of organization (Clements, 1983).

A preliminary exposure profile was developed through the use of simple stream flow models. To characterize ecological effects, SARs (Clements, 1988, 1994; Clements and Nabholz, 1994) were used to develop an initial toxicity profile or stressor-response profile (see Table 2-3 in

Section 2.3.3.2). There was low concern for acute or short-term exposures but high concern for chronic or long-term exposures.

The SARs, which were developed from actual testing of neutral organic compounds using surrogate species (U.S. EPA, 1982) that represented aquatic organisms in rivers and streams, predicted that fish would be the most sensitive group of aquatic species, with a predicted chronic value (ChV) of 0.002 mg/L (2 µg/L= 2 ppb). However, aquatic invertebrates (i.e., daphnids) also were predicted to be sensitive, with a ChV of 0.004 mg/L (4 µg/L= 4 ppb).

Assessment factors (U.S. EPA, 1984; Nabholz, 1991; Nabholz et al., 1993a; Zeeman and Gilford, 1993; Zeeman, 1995) were used to address uncertainties in extrapolating from laboratory to field effects. Investigators used a quotient method of ecological risk characterization to assess risk (Barnthouse et al., 1986; Nabholz, 1991; Rodier and Mauriello, 1993). If the results of the risk characterization predicted an unreasonable risk, OPPT assessors planned to perform a more in-depth analysis, including fate and transport modeling and ecological effects testing in accordance with ecological effects test guidelines (U.S. EPA, 1985). The PDM3 and EXAMS II exposure models would further characterize and refine exposure, and additional ecological effects testing of the PMN substance would be based on the criteria established by OPPT (U.S. EPA, 1983). Assessors would continue to use the quotient method to characterize risks.

2.3.3. Analysis, Risk Characterization, and Risk Management—First Iteration

2.3.3.1. *Characterization of Exposure*

Because the use of the PMN substance is claimed as CBI, only the terms *manufacturing*, *processing*, *use*, and *disposal* are used to describe the life cycle of the alkylated diphenyl. The sites of manufacture, use, and disposal and the actual releases (i.e., kg/day) that were used to calculate concentrations of the PMN substance in receiving rivers and streams also are considered as CBI. The production volume was estimated at more than 100,000 kg/year.

2.3.3.1.1. *Stressor characterization*. The alkylated diphenyl has low water solubility (<1 ppm) and is not expected to volatilize from water because of the low vapor pressure (Table 2-1). Photodegradation is negligible, and the compound is expected to sorb strongly to sediments. The half-life for aerobic degradation could be weeks; anaerobic degradation could require months or longer.

2.3.3.1.2. *Exposure analysis*. In the first iteration, OPPT assessors used a simple stream flow dilution model to calculate predicted environmental concentrations (PECs). The calculation was based on the following algorithm:

Concentration = releases (kg/day)/stream flow (millions of L/day)

The PEC calculations use both stream mean and low flow rates. In addition, the initial OPPT exposure analysis typically ranks stream flow rates and uses the 10% and 50% flow rates. The measured solubility limit of 0.300 mg/L was used.

OPPT assessors determined that there would be no significant releases during the manufacture of this PMN substance. The most significant routes of exposure would result from the use and disposal of the chemical. Effluents containing the PMN substance would first be treated in publicly owned treatment works (POTWs), which are wastewater treatment plants that include primary and biological treatment of the incoming waste stream. POTWs normally are located off-site or between the processing plant and the receiving river. To assess the extent of removal of the PMN substance by POTWs, OPPT assessors used data from laboratory-scale wastewater treatment experiments and their output from mathematical wastewater treatment simulations. The results indicated that removal would be due largely to adsorption to sludge; however, the analysis assumed approximately 10% of the PMN substance released from treatment was sorbed to solids in the effluent. This assumption was based on typical solids removal for secondary wastewater treatment systems.

Table 2-1. Physical/chemical properties of PMN substance

Property	**Measured or estimated value**
Chemical class	Neutral organic
Chemical name	CBI
Generic name	Alkylated diphenyls
Chemical structure	CBI
Physical state	Liquid
Molecular weight	232
Log K_{ow}	6.7[a]
Log K_{oc}	6.6[b]
Water solubility	0.051 mg/L (estimated)[c]
	0.300 mg/L (measured)
Vapor pressure	<0.001 Torr @ 20 °C[d]

[a]Estimated using CLOGP program (Leo and Weininger, 1985).
[b]Estimated by a regression equation developed by Karickhoff et al. (1979). The average method error for the log K_{oc} was 0.2 log K_{oc} units over a log K_{oc} range of 2 to 6.6.
[c]Estimated by a regression equation developed by Banerjee et al. (1980).
[d]Estimated by a regression equation cited in Grain (1982).

This study did not consider the fate and ecological effects of the PMN substance in sludges.

2.3.3.1.3. ***Exposure profile.*** Table 2-2 lists the PECs estimated at mean and low stream flows for the PMN substance during manufacture, use, and disposal.

2.3.3.2. *Characterization of Ecological Effects—Stressor-Response Profile*

OPPT assessors initially used SARs to estimate the ecological effects of the PMN substance as the result of a prenotice communication from the submitter. The potential submitter contacted EPA before submitting the PMN and was informed about OPPT's concerns for chronic toxicity. As a result, the submitter conducted and included the results of a fish acute toxicity test and a fish early life stage toxicity test of this alkylated diphenyl in its PMN submission. Table 2-3 summarizes the SAR-derived effect concentrations and the results of the fish acute and fish early life-stage toxicity tests.

2.3.3.3. *Risk Characterization*

Five risk characterizations were performed in this case study. Table 2-4 provides a brief summary of the assumptions, estimations, and types of uncertainty for each of the five iterations.

Table 2-2. Predicted environmental concentrations (PECs) for PMN substance (μg/L or ppb)

	Mean flow		Low flow	
Process	**10%[a]**	**50%**	**10%**	**50%**
Manufacture	0.0	0.0	0.0	0.0
Use	9.0	0.5	68.0	4.0
Disposal	52.0	0.7	90.0	6.1

[a]Percent of streams having flows equal to or less than the value used to calculate the PECs.

Table 2-3. PMN substance initial stressor-response profile

SAR estimated toxicity[a]		
Endpoint	**Effect concentration**	**Reference**
Fish 96-h LC_{50}	No effect at saturation	Veith et al. (1983)
Daphnid 48-h LC_{50}	No effect at saturation	Hermens et al. (1984)
Green algae 96-h EC_{50}[b]	No effect at saturation	Clements (1988, 1994)
Fish ChV[c]	0.002 mg/L	Broderius and Russom (1989)
Daphnid ChV	0.004 mg/L	Hermens et al. (1984)
Algal ChV	No effect at saturation	Clements (1988, 1994)
Actual measured toxicity submitted with PMN		
Fathead minnow (*Pimephales promelas*) 96-h acute test	No effect at saturation	U.S. EPA (1993)
P. promelas early life-stage test 31-day ChV (growth, mean wet weight)	0.013 mg/L	U.S. EPA (1993)
P. promelas early life-stage test 31-day ChV (survival, growth [length])	0.061 mg/L	U.S. EPA (1993)

[a]Based on molecular weight and K_{ow}.
[b]Median effect concentration.
[c]The ChV is the geometric mean of the highest treatment concentration for which no statistically significant effects were observed and lowest treatment concentration for which statistically significant toxic effects were observed. The ChV is the geometric mean of the maximum acceptable toxicant concentration and is also known as the chronic no-effect-concentration.

Table 2-4. Summary of five risk characterization iterations

Iteration	**Estimates/assumptions**	**Uncertainty**
1	Fish are the most sensitive species. CC set at 1 µg/L. PMN substance mixes instantaneously in water. No losses.	Worst-case analysis.
2	Actual test data for daphnids still indicate a CC of 1 µg/L. Determine how often this concentration is exceeded using PDM3.	Worst-case analysis. Other species may be more sensitive.
3	Estimate risk to benthic organisms using daphnid ChV and mitigation by organic matter. EXAMS II used to estimate concentrations.	Generic production sites. Actual data for benthic organisms not available.
4	Site-specific data obtained on use and disposal. EXAMS II rerun with new data.	Estimated toxicity for benthic invertebrates.
5	Actual test data for benthic organisms obtained.	Best estimates for identified sites. May not hold for other sites or uses.

2.3.3.3.1. ***Risk estimation: integration and uncertainty analysis via the use of assessment factors.*** OPPT assessors use the quotient method to estimate ecological risks. A quotient of 1 or greater indicates a risk. The algorithm is given below:

Risk quotient = PEC/CC

OPPT calculates the concern level or concern concentration (CC) by identifying the most sensitive species and effect from the stressor-response profile and dividing by an appropriate assessment factor (U.S. EPA, 1984). These assessment factors are akin to uncertainty factors but originally were designed to provide a risk-based rationale for requesting information and testing. The assessment factors developed and used by OPPT (see Table 2-5) are as follows: (1) 1,000 if only one acute value is available; (2) 100 applied to the most sensitive species when the environmental base set of toxicity data (i.e., fish acute toxicity, daphnid acute toxicity, and green algal toxicity) are available; (3) 10 applied to the lowest ChV (see Table 2-3, footnote c) for fish, daphnids, and algae; and (4) 1 applied to the ChV from a field study (e.g., pond) or from a microcosm study. Note that these assessment factors are designed to decrease in magnitude as more definitive toxicity data are made available to adequately assess the hazard profile of a new chemical.

In this case, OPPT assessors used the measured ChV of 0.013 mg/L from the fathead minnow early life-stage test rather than the estimated ChV of 0.004 mg/L for the daphnids that was based on a SAR (Table 2-3). To account for the uncertainty between chronic toxicity noted

Table 2-5. OPPT assessment factors used in setting "concern levels" for new chemicals

Available data on chemical or analogue	Assessment factor
Limited (e.g., only one acute LC_{50} via SAR/QSAR)	1,000
Base set acute toxicity (e.g., fish and daphnid LC_{50}s and algal EC_{50})	100
Chronic toxicity MATCs[a]	10
Field test data for chemical	1

[a]MATC = maximum acceptable toxicant concentration.
Source: EPA (1984); Nabholz (1991); and Zeeman and Gilford (1993).

in the laboratory and those that might occur in the field, an assessment (uncertainty) factor of 10 was used. The ChV was divided by this assessment factor to yield a CC of 0.0013 mg/L, which was rounded off to 0.001 mg/L or 1 µg/L (ppb).

In estimating risk, the CC of 1 µg/L was compared with the PECs (Table 2-2). As can be seen, the CC was exceeded at both the low and mean flow rates for 10% of the streams and at low flow for 50% of the streams. A chronic risk for the use and disposal of the chemical was inferred based on these stream flows.

It should be noted that the initial risk assessment evaluates risks to aquatic species in the water column only.

2.3.3.4. *Risk Management*

Because the results of the initial risk characterization identified a potential unreasonable risk, OPPT assessors recommended requesting a chronic daphnid test to complete the chronic tier tests. EPA also informed the submitter that a benthic test with contaminated sediments could be required if there was a potential unreasonable risk to sediment-dwelling organisms. The concern for benthic organisms was based on the high K_{ow}, low vapor pressure, and low water solubility, which indicate that this alkylated diphenyl was likely to partition to the sediments of rivers and streams, resulting in exposures of benthic organisms. EPA also requested a test that simulates the effectiveness of a POTW in removing the PMN substance from the waste stream.

2.3.4. Analysis, Risk Characterization, and Risk Management—Second Iteration

2.3.4.1. *Characterization of Exposure*

The coupled units test is a measure of the POTW removal of the PMN substance under conditions that simulate treatment in activated sludge. The POTW simulation conducted by the manufacturer indicated that a POTW would remove from 95% to 99% of the PMN substance.

2.3.4.2. *Characterization of Ecological Effects*

A 21-day daphnid chronic toxicity test of the chemical was conducted and was found to be valid and adequate for risk assessment purposes. The daphnid ChV for survival, growth, and reproduction was determined to be 0.007 mg/L (ppm) or 7.0 µg/L (ppb). This was found to be in excellent agreement with the SAR determined ChV of 4 ppb.

2.3.4.3. *Risk Characterization*

OPPT assessors then used these new data in a probabilistic dilution model (PDM3) (U.S. EPA, 1988) to estimate the number of days out of 1 year that the CC will be exceeded. OPPT assessors continued to use the CC of 1 µg/L or 1 ppb, since the daphnid ChV of 0.007 mg/L divided by the assessment factor of 10 also rounds off to 0.001 mg/L (ppm) or 1 µg/L (ppb). Like the simple stream flow model, PDM3 assumes that 1 day's release of the chemical will mix instantaneously with 1 day's flow of stream water in the receiving stream reach, and no losses will occur through any physical, chemical, or biological transformations after release. Stream flow rates for the proposed sites of use and disposal of this chemical were obtained from the U.S. Geological Survey stream reach database. Table 2-6 presents the results of PDM3.

2.3.4.3.1. *Interpretation of ecological significance*. As a matter of policy, OPPT infers a potential unreasonable risk to aquatic organisms if a CC based on chronic effects exceeds 20 days or more. The greater the number of days the CC is exceeded, the greater the potential risk. The 20-day criterion is derived from partial life-cycle tests (daphnid chronic and fish early life- stage tests) that typically range from 21 to 28 days in duration. OPPT infers low potential risk or no unreasonable risk if the CC is exceeded on fewer than 20 days. It is important to remember that the PDM3 model estimates only the total number of days out of 1 year that the CC is exceeded. The days are not necessarily consecutive, and thus the 20-day criterion is a conservative one. However, in practice, many low-flow days occur together during the same season for many stream reaches in the United States. The second iteration continued to show an unreasonable risk to aquatic organisms from the PMN substance because the CC of 1 ppb was exceeded on 20 days for use and 39 days for disposal (Table 2-6).

2.3.4.4. *Risk Management*

EPA notified the submitter that a potentially unreasonable risk to aquatic organisms still existed. A meeting was held to discuss possible benthic toxicity tests and to clarify unanswered questions regarding releases of the PMN substance through use and disposal. It also was decided to evaluate exposure further through the use of EXAMS II (Burns, 1989).

Table 2-6. PDM3 analysis[a]

Process	Exceedance (days/year)
Manufacture	0
Use	20
Disposal	39

[a]Releases to water in actual kg/d considered CBI. PMN substance was expected to be released 350 days/year, and a 95% removal by POTW was assumed.

2.3.5. Analysis, Risk Characterization, and Risk Management—Third Iteration

2.3.5.1. *Characterization of Exposure*

A preliminary EXAMS II analysis at the site expected to be at greatest risk indicated sediment concentrations ranging from 11.0 to 22.0 mg/kg (ppm) dry weight sediment after 1 year of releases of the PMN substance.

2.3.5.2. *Characterization of Ecological Effects*

Currently, there are no SARs for aquatic benthic organisms; however, SARs do exist for neutral organics with earthworms in artificial soil. To estimate the ecological effects of the PMN substance to aquatic benthic organisms, predictions from a fish 14-day LC_{50} SAR (Konemann, 1981) were compared with the earthworm 14-day LC_{50} SAR developed by OPPT assessors. The earthworm 14-day LC_{50} was about 10 times higher than the fish 14-day LC_{50} for the alkylated diphenyl. OPPT assessors concluded that the organic matter (i.e., ground peat) in the artificial soil could mitigate the toxicity of neutral organic chemicals by about 10 times.

OPPT assessors similarly expected that the organic matter found in natural sediments would mitigate the toxicity of the PMN substance by about another factor of 10, because natural organic matter in natural sediments should be more efficient at binding neutral organic chemicals than freshly ground peat in artificial soil. That is, sediment organic matter is likely to have a larger surface area-to-volume ratio than ground peat and, therefore, have more sites to bind hydrophobic compounds. Proceeding on the above assumption, the effective concentrations in the chronic toxicity profile for fish and daphnids were multiplied by 20 to produce the stressor-response profile for benthic organisms (Table 2-7). This scenario used the best data available at the time for neutral organic compounds, and the PMN submitter accepted the rationale for mitigation because it had no better data.

2.3.5.3. *Risk Characterization: Risk Estimation and Uncertainty Analysis*

The most sensitive endpoint was the proposed invertebrate 21-day ChV of 0.1 mg/kg. An assessment factor of 10 was applied to derive a benthic CC of 0.010 mg/kg (ppm) or 10 µg/kg (ppb). The quotient method was used. As can be seen from the above preliminary EXAMS II analysis, the exposure concentrations that were predicted exceeded the CC by factors of 1,000 to 2,000, and a risk to benthic organisms was inferred.

Table 2-7. Predicted stressor-response profile for benthic organisms

Organism	Endpoint	Effect level (mg/kg dry weight)
Invertebrate	14-day LC_{50}	0.300
Invertebrate	21-day ChV	0.100
Vertebrate	31-day ChV	0.300 to 1.0

2.3.5.4. *Risk Management*

As a result of these assessments of exposure and risk, the submitter initiated an extensive site-specific evaluation of the releases of the PMN substance during uses and disposal and forwarded this new exposure information to OPPT for evaluation. The report is CBI.

2.3.6. Analysis, Risk Characterization, and Risk Management—Fourth Iteration

2.3.6.1. *Characterization of Exposure*

OPPT used the additional information that was submitted to conduct a more comprehensive EXAMS II analysis. Table 2-8 summarizes the results for three specific use and disposal sites.

2.3.6.2. *Risk Characterization*

As can be seen from the information in Table 2-8, the sediment concentrations predicted from this refined exposure assessment were several orders of magnitude less than the preliminary EXAMS II analysis. As a result, there was not enough of a risk to benthic organisms to warrant a ban pending a testing decision by OPPT.

Table 2-8. EXAMS II analysis

Site	Water column (µg/L)	Sediments (mg/kg)
1	0.004	0.019
2	0.001	0.014
3	0.008	0.038

2.3.6.3. *Risk Management*

A decision was made by OPPT Division Directors to offer the submitter a consent order to allow manufacturing but require a benthic/sediment toxicity test to confirm the toxicity profile and thus the risk assessment. Before offering the consent order, the submitter volunteered to test with a benthic organism using clean natural sediment contaminated with known amounts of the PMN alkylated diphenyl. The submitter and OPPT agreed to a 28-day chironomid toxicity test using *Chironomus tentans*.

2.3.7. Analysis, Risk Characterization, and Risk Management—Fifth Iteration

2.3.7.1. *Characterization of Ecological Effects*

Table 2-9 presents the results of the chironomid toxicity test.

2.3.7.2. *Risk Characterization—Risk Estimation*

Using an assessment factor of 10, a CC of 2.0 mg/kg dry weight sediment was set for the benthic community based on the most sensitive effect, a ChV of 23 mg/kg for survival and emergence of chironomids. The sediment CC was 50 times higher than the highest PEC for sediments, and the ChV was an order of magnitude higher. Thus, there did not appear to be an unreasonable risk to benthic organisms as a result of the use and disposal of the PMN substance over a 1-year period.

As can be seen from Table 2-8, concentrations of the PMN substance at the specific sites of use and disposal were estimated to be two to three orders of magnitude lower than the CC of 1 µg/L that had been set for water column organisms.

Table 2-9. Stressor-response profile for *Chironomus tentans*

Endpoint	Effect concentration (mg/kg dry weight sediment)
14-day ChV	32
21-day EC_{50} emergence	23
25-day EC_{50} emergence	25
28-day EC_{50} emergence	24
28-day LC_{50} survival	22
ChV survival	23
ChV emergence	23

2.3.7.2.1. ***Uncertainty and assessment factors.*** In this study, the three main types of uncertainty with regard to ecological effects are variations in species-to-species sensitivity, uncertainty regarding acute versus chronic effects, and uncertainty regarding extrapolating laboratory-observed effects to those that might occur in the natural environment (Table 2-5). EPA (1984) developed these assessment factors specifically for establishing concern levels or concentrations for PMN substances. Their use was not intended to establish a "safe" level for a particular substance, but rather to identify a concentration that, if equaled or exceeded, could result in some adverse ecological effects. As can be seen above, such a finding provides the rationale for requesting either actual testing of the PMN substance and/or more specific information about fate and exposure. Naturally, there are other types of uncertainty, such as the effects of the PMN substance on adult rather than juvenile fish. Such types of uncertainty are considered research issues.

In the case of the exposure profile, an important aspect of uncertainty has to do with the actual duration of exposure. The PDM3 model predicts only the number of days out of one year the CC will be exceeded (Table 2-4). These days are not necessarily consecutive days. Thus, only flow rates could be used to account for seasonal variation. The presence or absence of critical life stages of aquatic organisms cannot be accounted for with this type of analysis. In addition, the generic nature of the assessment precludes identification of specific biota.

2.3.7.2.2. ***Risk description—ecological risk summary.*** This study demonstrates the utility of SARs in establishing toxicity profiles for aquatic organisms (fish, invertebrates, and algae). In this case, the chemical structures of the alkylated diphenyl indicated that the PMN substance was analogous to chemicals known to behave like neutral organic compounds. The high K_{ow} indicated that the substance would not be acutely toxic, and this was confirmed by an actual test with a surrogate fish species. Actual chronic toxicity testing in fish and daphnids confirmed the SAR-predicted chronic toxicity (well within an order of magnitude). EPA experience with other high K_{ow} compounds such as hexachlorobenzene and chloroparaffins further confirms the chronically toxic nature of such compounds. The predictions for chironomid toxicity did not agree with the actual test data. SARs have not been developed for benthic organisms simply because not enough test data are available to permit such analyses.

The use of SAR is not limited to neutral organic compounds. Currently, SARs are available for compounds that show more specific modes of toxicity or excess toxicity over the neutral organics. These SARs are organized by chemical class and examples include acrylates, methacrylates, aldehydes, anilines, benzotriazoles, esters, phenols, and epoxides (Clements, 1988, 1994; Auer et al., 1990; Clements and Nabholz, 1994).

Because the CCs were exceeded enough times out of 1 year, the PDM3 model indicated a risk to aquatic organisms. When actual sites were analyzed using EXAMS II, no unreasonable risks were identified.

2.3.7.2.3. ***Ecological significance.*** There appears to be no unreasonable risks to pelagic and benthic organisms at the identified use sites after 1 year's release. The potential risk posed by the PMN substance bioaccumulating through the aquatic food web was not thought to be significant during the first several years of use (see Section 2.3.7.2.5, Recovery Potential).

2.3.7.2.4. ***Spatial and temporal patterns of the effects.*** CBI restrictions preclude revealing the uses and specific sites for the PMN substance. However, OPPT assessors identified important river systems that could be impacted by this PMN substance. Thus, if there was a risk, the effects were not likely to be localized. However, given the restrictions in the consent order, any future risk will be localized to known sites.

2.3.7.2.5. ***Recovery potential.*** The PMN substance is a neutral hydrophobic chemical. This mode of toxicity is akin to a simple narcosis type of action (Auer et al., 1990; Veith and Broderius, 1990) that is reversible if exposure to the toxicant is terminated before lethality or death occurs.

The recovery potential was not evaluated. Exposures over a year were predicted to have a low potential to cause adverse effects. However, continued exposure at the same site for a number of years may cause some impact to benthic organisms, but OPPT does not regulate multiyear exposures to the aquatic environment because of the greater degree of uncertainty about future production volume and uses. OPPT assessors warned the submitter that continued release of this alkylated diphenyl at one site could cause environmental problems in the future. Since the alkylated diphenyl was predicted to be persistent in sediments and was expected to continue to accumulate in sediments, the submitter could be liable for cleaning up any sediments contaminated with this alkylated diphenyl after a decade or so of continuous use at the same site(s).[1]

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[1]The final regulatory decision was a significant new use restriction (SNUR, see Risk Management - Final Decision) that limited the releases to surface water to 1 µg/L (ppb). OPPT technical staff advised the submitter's contractors and technical contact that release of this chemical from one site over an extended period could lead to contaminated sediments and that the company might be liable for cleanup if monitoring determined that the sediments were sufficiently contaminated. Use of this PMN chemical substance began in 1993. As a SNUR was attached to the PMN the submitter had to inform the users and local regulatory authorities about the SNUR and its limitations. This resulted in the environmental protection agency of a midwestern State monitoring the PMN substance in the sediments and the fish of a stream receiving effluent containing the PMN substance. In 1997 the State EPA monitoring efforts found measurable concentrations of the PMN substance in sediments and in fish fillets. The concentrations in fish fillets were determined to range as high at 1.65 mg/kg (ppm) fresh weight.

2.3.7.3. *Risk Management—Final Decision*

The OPPT Division Directors and other risk managers agreed that the PMN substance posed no unreasonable risks to pelagic aquatic organisms at the specific sites of use and disposal. However, there could be risks at other sites through the use and disposal of the PMN substance. Therefore, the final disposition was a *significant new use restriction* (SNUR), including a restriction against releasing concentrations higher than 1 µg/L (the concern level for the PMN substance). The submitter must also submit a *significant new use notice* if it wants to use the PMN substance at sites other than the ones identified in its submission.

2.3.8. Discussion of Case Study

As outlined in Figure 2-1, this is an example of how the Framework for Ecological Risk Assessment (U.S. EPA, 1992) and the Guidelines for Ecological Risk Assessment (U.S. EPA, 1998) are consistent with the underlying structure of a new chemical assessment by OPPT. It is also a real-world demonstration of the iterative manner in which the ecological risk assessment of new industrial chemicals can be evaluated by EPA.

A large majority of the new chemical evaluations performed by OPPT do not make such a risk-based case and therefore do not need to undergo this level of assessment. Even though this evaluation may not be typical of a new chemical, it proved useful in illustrating (1) the depth of ecological risk assessment that is feasible in OPPT, (2) the routine and pragmatic use that has been made of SAR, and (3) the routine and pragmatic use of the assessment (uncertainty) factors that were developed by OPPT for new chemical evaluations (U.S. EPA, 1984).

Discussion of the empirical basis for the development of these assessment factors is to be found in the OPPT report on how concern levels (i.e., concern concentrations) in the environment are to be determined by the use of these assessment factors (U.S. EPA, 1984). This simple approach also is mentioned and elaborated on in other, more recent publications (Auer et al., 1990; Nabholz, 1991; Zeeman and Gilford, 1993; Zeeman et al. 1995).

Indeed, the simple assessment factor method developed by OPPT in the early 1980s remains a very pragmatic and effective tool for estimating the levels of concern (risk) for industrial chemicals released into the aquatic environment. Its use has been supported by analyses comparing it with more complex statistical methods (Calabrese and Baldwin, 1993; Forbes and Forbes, 1993, 1994; Zeeman, 1995).

2.3.9. Summary of Case Study

This is a relatively comprehensive example of OPPT's capabilities in conducting ecological risk assessments for new chemical substances. It illustrates the consistency among OPPT's approach, EPA's 1992 Framework document, and EPA's 1998 Guidelines for Ecological Risk Assessment.

The essential features in this case study reflect several practical considerations. TSCA requires the manufacturer or importer of new industrial chemicals to submit a PMN to EPA 90 days before it intends to begin manufacturing or importing. Because actual test data are not required to be developed as part of a PMN submission, OPPT must frequently use SAR to estimate both ecological effects and exposure/fate characteristics (such as physical/chemical properties and biodegradation). Because test data for new chemicals are seldom available, an empirical set of assessment factors (or uncertainty factors) was developed by OPPT and are routinely used in the ecological risk assessment of PMNs.

This study focuses on the assessment of a PMN substance, i.e., an alkylated diphenyl, that is a neutral organic compound. Chemicals belonging to this class of compounds elicit a nonspecific and simple form of toxicity known as narcosis. The toxicity of neutral organic compounds can be estimated through SARs that correlate toxicity with the octanol-water partition coefficient (K_{ow}) and molecular weight. The subject PMN substance had a predicted log K_{ow} of 6.7. Compounds with such a high log K_{ow} are not expected to be acutely toxic (i.e., no acute effects at saturation over short-term exposure durations), but are expected to elicit chronic effects following long-term exposures. Actual testing of the PMN substance confirmed these predictions of ecotoxicity.

The PMN submitter identified processing, use, and disposal sites adjacent to rivers and streams since the chemical was to be imported into the United States. Because it was expected that the PMN substance would be discharged into such environments, pelagic and benthic aquatic populations, communities, and ecosystems were considered to be at risk. Therefore, the assessment endpoint used in this study was the protection of aquatic organisms (e.g., fish, aquatic invertebrates, and algae). Measurement endpoints used to evaluate the risks to aquatic organisms (the assessment endpoint) were mortality, growth and development, and reproduction.

Initial exposure concentrations were estimated using a simple dilution model that divided releases (kg/day) by stream flow (millions of liters/day). Subsequent exposure analyses used a probabilistic dilution model and the exposure analysis modeling system. PDM3 was used to estimate the number of days a particular effect concentration would be exceeded in 1 year, and EXAMS II was used to estimate concentrations in the water column and in sediments using site-specific data.

Toxicity initially was predicted by the use of SAR. Aquatic toxicity test data accompanying the PMN submission and later receipt of additional test data confirmed the accuracy of these SAR predictions. Assessment (uncertainty) factors were used to determine the concern level or concern concentration (CC) in the receiving stream. This stream water-column CC was set at 1 µg/L (ppb). When the OPPT risk assessment determined that this CC was exceeded for more than 20 days, a potential unreasonable risk was assumed to be expected if this PMN chemical substance was allowed to be used.

In risk characterization, the quotient method was used to compare exposure concentrations with the ecological effect concentrations. A ratio of 1 or greater indicated a potential risk. The PMN evaluation resulted in five iterations of analysis and risk characterization. The first four iterations identified an ecological risk and resulted in the collection of additional and more specific ecological effects test data and more detailed information on potential exposures to the PMN substance. The final outcome was that the PMN substance could be used only at the identified sites because there was uncertainty as to whether the concern level (1 µg/L) might be exceeded at sites not identified and characterized by the submitter.

2.4. RISK ASSESSMENT METHODOLOGY DEVELOPMENT

The OPPT methodology for the ecological risk assessment of new chemicals was developed more than a decade ago (Zeeman and Gilford, 1993) and reflects several regulatory constraints within which OPPT had to operate. There was a need to assess large numbers of new chemicals, typically in a short time frame and typically with a minimal level of data provided with which to perform this risk assessment (i.e., seldom were physical/chemical properties, environmental fate, or ecotoxicity data provided). From these restrictions it was obvious that the methods of ecological risk assessment used by OPPT had to be very pragmatic. Ecological risk assessors from OPPT were involved in and played a major role in the development of the EPA framework and guidelines documents. Therefore, the extant OPPT methodology for ecological risk assessment proved to be both useful and illustrative in the development of many of the principles and practices espoused in each of these documents.

2.5. RISK MANAGEMENT

As is evident from the new chemical assessment case study above, there were five iterations in characterizing the risk of this chemical to organisms in the environment (Table 2-5). It is also plain that the risk management decisions made here played a key role in deciding on the next steps for each of these iterations. This case study is illustrative of how an efficient and pragmatic ecological risk assessment process can assist in eliciting reasonable risk management decisions. These risk management decisions helped to develop the kinds of information needed to perform an adequate risk assessment and to come to closure on the regulatory actions determined to address and/or mitigate the ecological risks expected from allowing the use of this chemical.

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3. ECOLOGICAL RISK ASSESSMENT UNDER FIFRA

3.1. SUMMARY

The ecological risk assessment methodologies under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) are consistent with current ecological risk assessment guidelines (EPA, 1998). FIFRA requires prospective assessments of pesticides in a tiered framework. Typically, the industry generates environmental fate and effects data and submits it to the EPA Office of Pesticide Programs (OPP). OPP evaluates the data and conducts the risk assessment.

This chapter discusses the generalized process for effects and exposure analyses and assessment methods. For effects analysis, the tiers move from acute toxicity test data to subchronic and chronic toxicity data to field, farm, pond, or mesocosm studies. In exposure analysis, level 1 uses conservative assumptions in exposure models. These are refined with site-specific data, pesticide use information, use of more complex exposure models, and the application of probability modeling in higher levels. In risk characterization, the quotients (exposure/effects) are used at lower tiers, with more complex methods often used at higher tiers.

The registration and reregistration of pesticides under FIFRA is a cost-benefit statute that balances no unreasonable adverse effects to human health or the environment with economic issues, societal concerns, and political and legal factors. Ecological effects are often mitigated through reduction in application frequency, dose, specific crop or area use, or other restrictive requirements.

3.2. INTRODUCTION

This chapter discusses ecological risk assessment methods and approaches used by EPA's Office of Pesticide Programs (OPP). The chapter's specific objectives are to:

- Provide a regulatory context for ecological risk assessment under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

- Discuss ecological risk assessment in pesticide regulatory operations as part of a broader risk management and decision-making context

- Summarize the application of the ecological risk assessment in risk management decision making.

3.3. REGULATORY CONTEXT FOR PESTICIDE REGISTRATION AND REREGISTRATION

FIFRA gives EPA the authority to register pesticides to ensure no unreasonable adverse effects to human health or the environment, taking into account the economic, social, and environmental costs and benefits of the pesticide use. As such, FIFRA is a cost-benefit statute, and an "unreasonable adverse effect" on the environment is a regulatory determination that must account for scientific as well as economic, social, and governmental cost and benefit factors. Under FIFRA authority, EPA regulates insecticides, herbicides, fungicides, rodenticides, disinfectants, plant growth regulators, biological agents, and other pest control agents. The primary regulatory vehicle under FIFRA is the pesticide label. Every registered pesticide product must bear a label that includes the producer number, product registration number, active ingredient statement, warning or precautionary statements, and directions for use.

EPA's Office of Pesticide Programs currently reviews about 5,000 pesticide registration submissions annually. The scope of the submissions ranges from simple label amendments to registration of new active ingredients. Since 1947, thousands of pesticide products have been registered. Perhaps not surprisingly, standards for approval and test data requirements reflect changes in science and pesticide regulatory policy over time. To ensure compliance with current scientific and regulatory standards, FIFRA also requires the review and reregistration of existing pesticides. During reregistration, registrants may delete pesticide uses or voluntarily withdraw products or uses. Further, EPA has the authority to cancel registrations for pesticide products that do not meet the requirements for reregistration. Since 1988, the registered products subject to reregistration have declined from approximately 50,000 to about 20,000.

Following registration or reregistration, problems that arise during the use of a particular pesticide may be investigated under the special review process. Special review consists of scientific and legal analysis before a major regulatory decision is made on a registered pesticide. Special review is conducted by notice-and-comment rulemaking. Science issues are developed and presented to the FIFRA Scientific Advisory Panel for review. Additionally, the U.S. Food and Drug Administration and congressional committees are invited to provide formal comments. Once a decision is made, the registrant may appeal the decision through administrative procedure or judicial review.

3.4. RISK MANAGEMENT

Ecological risk assessment in pesticide regulatory operations is best viewed as the application of regulatory science in a risk management context. This view is supported by emerging risk-based approaches to environmental regulations (Thomas, 1987; Science Advisory Board, 1990a,b,c,d), which promote increased integration of societal values, science, and risk mitigation practices. The integrated decision-making process involves the following three interactive phases:

1. **Risk assessment** is a science-based activity that consists of hazard characterization and exposure characterization and ultimately integrates the two into a risk characterization.

2. **Risk mitigation** involves remediation or mitigation measures to reduce or eliminate source contamination and adverse environmental impacts.

3. **Risk management** is a policy-based activity that defines risk assessment questions and endpoints to protect human health and the environment. It takes the scientific risk assessment; incorporates social, economic, political, and legal factors that impinge on or influence the final decision; and selects regulatory actions.

The underlying principles behind risk reduction and integrated decision making are detailed in the strategic initiatives and guiding principles recently released by EPA (1994) and include ecosystem protection, pollution prevention, strong science and data, partnerships, and environmental accountability. In essence, the emerging policies are directed toward greater participation in environmental problem solving and decision making, including risk assessors, risk managers, and parties affected by the decision (regulated community, user groups, environmental interest groups, general public, and scientists).

Improved understanding of the different perspectives of risk assessors and risk managers is crucial to the ultimate success of integrated decision-making processes. Risk assessors are generally concerned with performing risk assessments in the most scientifically credible manner and identifying additional data or research to better characterize risk.

In contrast, risk managers have little interest in the scientific nuances or technical details surrounding an ecological risk assessment. Rather, they may be primarily concerned with integrating ecological risk conclusions into a broader risk or risk-benefit framework to finalize regulatory decisions. The decision may include imposing risk reduction or risk mitigation control practices rather than undergoing successive iterations of the original risk assessment. Risk reduction or risk mitigation activities are becoming increasingly important risk management tools. For pesticides, such activities frequently include changes in or restrictions for specific uses, manifested as label changes.

Risk assessors must be aware of risk management needs in the problem formulation stage to ensure that the assessment endpoints and resolving power that the decision maker requires are understood. Ideally, discussions should occur during a formal a priori problem formulation step in the assessment process. Once risk assessors and risk managers have agreed on assessment goals and objectives, it falls to the risk assessor to design and conduct the risk assessment. Routine problem formulation that engages both risk assessors and risk managers is increasing, but has not been commonly practiced in the past. This has sometimes led to differing expectations between risk assessors and risk managers regarding the objectives, scope, and application of a risk assessment. The importance of promoting formal problem formulation cannot be overstated.

3.5. RISK ASSESSMENT METHODS IN PESTICIDE REGULATORY OPERATIONS

Registration and reregistration decisions are based in part on the evaluation, synthesis, and integration of pesticide studies conducted by registrants and submitted to the Agency. Studies are routinely conducted in mammalian toxicology, occupational and residential exposure, environmental fate and transport, and ecological effects. Individual studies are evaluated by EPA scientists and subsequently used in human health and ecological risk assessments. The risk assessments are then used by regulatory decision makers, who make the final risk management decisions. Only ecological risk assessment will be further considered here.

Ecological risk assessment methods and procedures under FIFRA are detailed elsewhere (40 CFR 158.130; 40 CFR 158.145; Urban and Cook, 1986; Fite et al., 1988; Touart, 1988; SETAC, 1994; Touart, 1995; Touart and Maciorowski, 1997) and only briefly described here. Existing methods predate EPA's ecological risk assessment framework (U.S. EPA, 1992) and guidelines (U.S. EPA, 1998). However, two pesticide case studies (carbofuran, synthetic pyrethroids) were used in the Agency's state of the practice for ecological risk assessment prepared during the guidelines development process (U.S. EPA, 1993). Further, the traditional FIFRA ecological risk assessment approach is consistent with the ecological risk assessment framework process and includes problem formulation, exposure characterization, effects characterization, and risk characterization.

Generally, ecological risk assessments for pesticide registration are prospective estimates based on single active ingredients and use sites (e.g., corn, wheat, ornamental plants, etc.). The scope and complexity of any specific pesticide risk assessment will vary with the specific chemical and use, but a tiered iterative approach is generally used. The tiers progress from simple risk quotients derived from laboratory fate, transport, and toxicity data in early tiers to a weight-of-evidence approach in later tiers (Tables 3-1 and 3-2).

Exposure analysis may consist of a preliminary or comprehensive fate and transport assessment (Table 3-1) based on registrant-submitted data. The exposure analysis provides exposure profiles and estimated environmental concentrations (EEC) for the pesticide use (e.g.,

Table 3-1. Generalized exposure analysis and assessment methods and procedures used in prospective ecological risk screens of pesticides[a]

Preliminary exposure analysis includes simple laboratory tests and models to provide an initial fate profile for a pesticide (hydrolysis and photolysis in soil and water, aerobic and anaerobic soil metabolism, and mobility).

Fate and transport assessment provides a comprehensive profile of the chemical (persistence, mobility, leachability, binding capacity, degradates) and may include field dissipation studies, published literature, other field monitoring data, ground-water studies, and modeled surface water estimates.

Estimated environmental concentrations (EEC) are derived during the exposure analysis or comprehensive fate and transport assessment. There are four EEC estimation procedures:

> Level 1: A direct-application, high-exposure model designed to estimate direct exposure to a nonflowing, shallow-water (<15 cm) system.
>
> Level 2: Adds simple drift or runoff exposure variables such as drainage basin size, surface area of receiving water, average depth, pesticide solubility, surface runoff, or spray drift loss, which attenuate the Level 1 direct application model estimate.
>
> Level 3: Computer runoff and aquatic exposure simulation models. A loading model (SWRBB-WQ[b], PRZM[c], etc.) is used to estimate field losses of pesticide associated with surface runoff and erosion; the model then serves as input to a partitioning model (EXAMS II[d]) to estimate sorbed and dissolved residue concentrations. Simulations are based on either reference environment scenarios or environmental scenarios derived from typical pesticide use circumstances.
>
> Level 4: Stochastic modeling where EECs are expressed as exceedance probabilities for the environment, field, and cropping conditions.

[a]For additional details regarding environmental fate data requirements, see 40 CFR § 158.130, SETAC (1994), and Touart (1995).
[b]Simulator for Water Resources in Rural Basins--Water Quality.
[c]Pesticide Root Zone Model.
[d]Exposure Analysis Modeling System.

Table 3-2. Generalized ecological effects analysis and risk quotient methods and procedures used in prospective risk screens of pesticides

Tier I effects analysis provides acute toxicity values and dose-response information (mammalian and avian acute oral LD_{50}; avian dietary LC_{50}; seedling emergence and vegetative vigor EC_{25}; honeybee acute contact LD_{50}; and additional wild mammal, estuarine, and plant tests depending on pesticide use category).

Tier II effects analysis provides subchronic and chronic toxicity values (NOEC) including avian reproduction studies; special avian or mammal studies; fish early life stage studies; invertebrate life cycle studies; and a fish bioaccumulation factor.

Tier III effects analysis provides refined NOEC estimates for chronic toxicity that may include a fish full life cycle test, aquatic organism accumulation, or food chain transfer tests

The quotient method is used to provide a set of acute and chronic risk quotients (RQ) for fish, birds, invertebrates, plants, and endangered species. The RQs are calculated by dividing exposure (EEC) by hazard (LD_{50} or LC_{50} or NOEC). Risk quotients are then compared to regulatory risk criteria as follows:

Presumption of acceptable risk	Presumption of risk that may be mitigated by restricted use	Presumption of unacceptable risk	
		Nonendangered species	**Endangered species**
Acute toxicity EEC<0.1 LC_{50}	0.1 LC_{50} ≤ EEC ≥ 0.1 LC_{50}	EEC ≤ 0.50 LC_{50}	EEC≤ 0.05 LC_{50} or EC≤ 0.10 LC_{10}
Chronic toxicity EEC≤ chronic NOEC	N/A	EEC > NOEC	EEC > NOEC

Tier IV effects analysis allows registrants to rebut a presumption of risk derived from laboratory studies by performing field or simulated field studies, including qualitative terrestrial field studies, farm pond studies, mesocosm studies, or other special studies.

[a]For additional details regarding ecological effects data requirements, see 40 CFR § 158.145 Subdivision E; Urban and Cook, 1986; SETAC, 1994; and Touart, 1995.

corn, cotton, wheat, etc.). Note that EECs may be derived from four estimation procedures ranging from simple to complex. The ecological effects analysis (Table 3-2) is also tiered. Tier I provides an acute toxicity profile for birds, fish, mammals, and invertebrates. Tier II provides a subchronic and chronic toxicity (no-observed-effects concentration, or NOEC) profile and bioaccumulation potential for the same test species. Depending on the hazard and exposure characteristics of a particular pesticide and use pattern, Tier II analyses may be conducted for all representative taxa, or may focus on either aquatic or terrestrial species. When warranted, Tier III effects analysis is used to refine NOEC and bioaccumulation estimates.

Following exposure and effects analysis, ecological risk is estimated as a function of ecotoxicological effects and environmental exposure using the quotient method (Table 3-2). A number of risk quotients are calculated (e.g., acute avian, acute fish, acute invertebrate, chronic avian, chronic fish, chronic invertebrate, etc.) and compared with regulatory risk criteria (e.g., presumption of acceptable risk, presumption of unacceptable risk, etc.). Traditionally, if regulatory criteria are exceeded, a high-risk potential is assumed to exist for the pesticide-use combination. If a registrant wishes to refute a presumption-of-risk finding, a Tier IV effects analysis, consisting of field studies, simulated field studies, or other special studies, may be conducted (Fite et al.,1988; Touart, 1988).

3.5.1. Application of Ecological Risk Assessments in Pesticide Regulatory Decision Making

The application of ecological risk assessments in pesticide regulatory decisions is subject to practical constraints imposed by law, regulatory policy, and precedent. In October 1992, EPA’s Office of Prevention, Pesticides, and Toxic Substances (OPPTS) released a set of policy decisions following a comprehensive review of ecological and environmental fate data requirements for registration and reregistration of pesticides. Issues considered in the review included resource requirements necessary to review data, the utility of data in assisting regulatory decision making by risk managers, and the impact of data requirements on meeting congressionally mandated deadlines for the reregistration of pesticides already in use. Major points of the policy decisions are paraphrased below.[2]

- Establish risk-based priorities to allow protective decisions in a timely fashion.

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[2]In response to the OPPTS policy decisions, a number of actions were initiated by OPP to develop a strategy for implementation. Foremost was the development of the Ecological Fate and Effects Implementation Work Group. This group developed an implementation strategy that subsequently led to the formation of the Aquatic Risk Assessment and Mitigation Dialogue Group. The mission of the Dialogue Group was to discuss pesticide risk assessment and risk reduction for aquatic systems and recommend methods and use of risk mitigation measures in regulatory decision making. The background material leading to the Dialogue Group and its deliberations and final recommendations is detailed in SETAC (1994) and summarized briefly here.

- Base decisions primarily on laboratory studies, with less dependence on terrestrial and aquatic field studies.

- Provide better integration of risk assessment and risk management processes.

- Use risk mitigation to the extent feasible to achieve acceptable risk reduction.

- Develop the concept of continuous improvement and develop strategies to characterize long-term ecological risk with less uncertainty.

Aquatic field studies or simulated field studies were conducted with the objective of rebutting the presumption of risk identified when regulatory criteria as described in Tables 3-1 and 3-2 were not met. The policy recommendations, using the same methods and procedures, promote environmentally protective decisions through early application of mitigation actions to reduce the off-field movement of pesticides, and therefore reduce risk to nontarget organisms. There are also provisions for more sophisticated assessment procedures, which allow for probabalistic estimates of levels of concern. The use of mitigation and monitoring also shifts the assessment from a solely a priori process to one of a posteriori monitoring and mitigation. The sections of the document that follow represent a proposed set of procedures to implement mitigation and to assess the efficacy of mitigation and the adequacy of the risk assessment procedure.

3.5.2. The Risk Identification and Mitigation Process

Pesticide registration and reregistration processes are considered to be iterative, as presented in Tables 3-1 and 3-2. That is, the database supporting the current registration status of a pesticide will be periodically reviewed and evaluated to ensure that it meets current scientific requirements, standards, and regulatory policies. The verification of risk mitigation steps is based on this cyclic evaluation of the pesticide in light of new or additional information. For the purpose of discussion, the risk identification/mitigation process begins any time a pesticide is reviewed for the purpose of registration or reregistration.

When a pesticide undergoes evaluation for registration or reregistration, the scientific experts review and evaluate the data available in a comprehensive manner to ensure it meets the standards established for carrying out risk assessments. The database is evaluated and integrated in such a manner that routes of dissipation, significant environmental degradates, residue levels, and time of persistence of degradates in the various environmental compartments are elucidated.

This information, along with the hazards of the pesticide as determined in the required studies and available incident data, is used to determine what level of concern exists in each of several compartments in the environment. If a level of concern is unacceptable, then risk mitigation/verification procedures are initiated.

In the registration and reregistration processes, a conclusion that an unacceptable risk will result from the proposed or registered use(s) of pesticides is immediately passed to the appropriate divisions within OPP. The Registration Division and Special Review and Reregistration Division pass this information on to the registrant(s). The purpose of notification is to ensure that everyone is actively involved in the process of identifying appropriate risk reduction measures. Once OPP and the registrant(s) have concluded their work on appropriate risk mitigation steps, negotiations between OPP and the registrant(s) on the label changes necessary to reduce the risk begin.

The product of the negotiation is a set of mitigation actions, to which OPP agrees, that effectively reduce the risk to an acceptable level. As this process begins, data to support the effectiveness of the mitigation steps will be nonexistent or limited in scope. To ensure the effectiveness of the mitigation steps, the Agency may require some sort of verification data. Once mitigation measures have been identified and implemented, post-registration or post-reregistration monitoring may be required to verify the efficacy of the risk mitigation measures. Quantifiable verification of effectiveness of the mitigation may take several years. The verification data would then be reviewed to evaluate the effectiveness of the mitigation measures.

3.6. RISK ASSESSOR AND RISK MANAGER COMMUNICATION

Once an ecological risk characterization is passed to a risk manager, additional communication and discussion is necessary. Presented with a scientific evaluation of risk, the risk manager may want additional information or study, or may need to act on the information in hand regardless of its scientific strengths or shortcomings. Rather than refine the risk assessment, a risk manager may opt to impose mitigation to reduce the risk, even in the face of uncertainty that the mitigation will be effective. When such situations occur, risk assessors must clearly and succinctly summarize risk, uncertainties, and options for the benefit of risk managers, stakeholders, and the public at large. Further, risk assessors must be willing to discuss the relative merits of risk mitigation even in the absence of data.

Although there is general agreement that risk assessors need to be involved in risk management decisions, their involvement is also important to ensure the scientific integrity of the risk assessment process. Once a risk characterization is used to reach a decision, the risk assessor rarely has an opportunity to request more data or information on which to base opinions or recommendations. More important, the risk assessor has now moved into the risk management arena. In the risk management decision process, the risk assessor may be asked to analyze or judge the effect of proposed risk mitigation on the original risk assessment. This does not change the original risk assessment, which serves as a baseline estimate, but the analysis may begin here as to whether management actions such as mitigation will reduce risk to acceptable levels.

Until the overall integrated decision-making process is better defined and understood by both risk assessors and risk managers, there undoubtedly will be some controversy regarding the application of ecological risk assessments in regulatory operations. However, recognizing and understanding that risk assessors and risk managers have different roles and responsibilities should go a long way toward improving the decision process.

3.7. NEXT STEPS

Although the process described above has been partially implemented in decision making, full implementation requires action on the following recommendations promoted by the Dialogue Group (SETAC, 1994). EPA-OPP is actively pursuing these recommendations through technical committees.

- Integrated probabilistic risk assessments that include both the probability of exposure and effects should be implemented within OPP.
- Improved capabilities for predictive risk assessments through tiered modeling and focused laboratory studies should be encouraged, and when conducted should be included as part of the risk assessment.
- Mitigation must provide meaningful ecological risk reduction, be pragmatic and achievable, and consider the need for timely decisions and cost-effective utilization of financial and human resources.
- The effectiveness of the paradigm in improving the ability of EPA to implement timely protective environmental decisions must be monitored and evaluated on a routine basis.

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4. NONINDIGENOUS SPECIES

4.1. SUMMARY

Traditionally, ecological risk assessment has been applied to chemical stressors. This chapter shows how ecological risk assessment principles can be used to evaluate biological stressors, including nonindigenous species and genetically engineered organisms. Biological stressors are unique in their ability to reproduce, adapt to new environments, and evolve over time. The concept of exposure for biological stressors includes evaluating potential entry sources and pathways as well as describing their potential for colonization and spread. In general, the case studies in this chapter follow the same logical sequences and steps outlined in EPA's ecological risk assessment guidelines. However, in contrast to EPA's guidelines, which keep the risk management and risk assessment processes separate (but coordinated), two of the case studies in this chapter (black carp and pine shoot beetle) include risk management considerations such as socioeconomic impacts as part of their risk assessment approach.

Black carp are native to eastern Asia and have been proposed for introduction into the United States. The black carp case study illustrates a cost-benefit issue in which the potential for positive gain from intentional introductions (biological control of yellow grub parasites in fish ponds and of the zebra mussel in the wild) needs to be balanced with the potential for economic and/or environmental damage resulting from establishment of the black carp in the wild. Risk was estimated by an expert judgment process that combined estimation of the probability of establishment (organism in entry pathway, entry potential, colonization potential, and spread potential) with the consequences of establishment (environmental, economic, and perceived—social and political). Qualitative risk rankings (high, medium, or low risk) were accompanied by detailed descriptions of the rationale for each rating. An overall judgment of unacceptable risk was assigned to uncontrolled releases of black carp.

The second case study evaluates risks associated with release of recombinant rhizobia at a small-scale agricultural field site. This case was written at the request of EPA's Risk Assessment Forum to test the utility of EPA's Framework for Ecological Risk Assessment (U.S. EPA, 1992) with genetically engineered microorganisms. This case study was developed from a submission received by EPA under the Toxic Substances Control Act (TSCA) premanufacture notification (PMN) provision (see Chapter 2). In this case, there was concern over the possible effects that might result from field testing of recombinant rhizobia (symbiotic bacteria) intended to increase yields of alfalfa. Risks were characterized as low, primarily because off-site movement of the recombinant rhizobia was considered very unlikely. One positive aspect of the case was the use of postassessment monitoring to verify risk predictions.

The third case study involves concerns over introduction of the pine shoot beetle into the United States on imported logs. The pine shoot beetle can cause serious damage to the new growth of healthy trees as well as to weak and dying ones. Scenario analysis was offered as a methodology to evaluate the pathways and variables contributing to the pest risk and to identify the options to mitigate the risk. An interesting facet of this case was the application of expert opinion to quantify risks of different scenarios. The product of this effort provides a basis for evaluating and adjusting risk management options and quarantine regulations.

Using risk assessment to evaluate nonindigenous species provides a framework for placing available information into a format that can be used and understood by policy makers for making risk management decisions. The major difficulty is the high uncertainty associated with predicting the outcome of a nonindigenous species in a new environment, given the lack of information on specific organisms and our current state of understanding on how an ecosystem functions. Nevertheless, the degree of uncertainty surrounding the introduction of nonindigenous organisms only increases the need for careful, unbiased risk assessments before making a decision for or against an introduction.

4.2. INTRODUCTION

4.2.1. Definition and Scope of Risk Analyses

Humans have moved plants and animals from one ecosystem to another throughout recorded history. Organisms moved outside their historic or natural geographic range are considered nonindigenous species. Within the United States, this includes species imported into the country as well as those moved from one bioregion to another. In the United States, nonindigenous species have been referred to as “exotics,” “transplants,” “nonnatives,” or “introduced species.” In foreign countries, they often are called “alien” species.

In the United States alone, humans have intentionally or unintentionally introduced more than 4,500 foreign species that have established and spread (OTA, 1993). Many introductions have been viewed as providing economic and social benefits. However, the economic and environmental consequences of some introductions have been harmful, and in a few cases catastrophic.

The definitions given below are generally consistent throughout risk analyses involving nonindigenous species:

- Nonindigenous species—the condition of a species being beyond its natural range or natural zone of potential dispersal; includes all domesticated and feral species and all hybrids except for naturally occurring crosses between indigenous species (OTA, 1993).

- Pathway—any means by which nonindigenous species are transported.

Evaluations of nonindigenous species, independent of the method or process used, generally contain one or more of the following components:

- Identification of one or more nonindigenous species of concern or the identification of a pathway transporting or vectoring nonindigenous species of concern

- Determination of the likelihood that these nonindigenous species could become established

- Determination of the impact if the nonindigenous species became established

- Determination of the available actions to reduce the risk that the nonindigenous species will cause unacceptable damage.

4.2.2. Relationship to EPA's Ecological Risk Assessment Framework

This chapter discusses risk analyses that are directed toward evaluating and reducing the negative impact from the establishment of "new" nonindigenous species. Risk analyses triggered by nonindigenous organisms already established falls beyond the purview of this chapter and more into the specific methods of pest control or the more general realm of ecosystem management.

This chapter presents three case studies to illustrate the applicability and efficacy of risk analysis as it applies to a range of nonindigenous species problems and issues. These case studies were chosen because each represents different types of nonindigenous species (a fish introduction, a genetically engineered bacteria, and a forestry beetle pest) and because each study explores different types of risk evaluations (risk assessment focus, risk management focus, and qualitative and quantitative evaluations). Only a summary of the risk analysis for each of the case studies is presented in this chapter. Details on the risk processes and methodologies used can be found in the original risk documents.

The main difference between physical/chemical ecological stressors and biological stressors is that biological stressors are capable of reproducing. Equally important is the characteristic of a biological organism to control its behavior so that it can adjust to or modify the environment to fit its needs. In addition, a newly established population can, over successive generations, change (evolve) to better adapt themselves to the new environment. These basic characteristics of life add a new dimension of complexity and uncertainty that has little parallel with risk analyses on nonliving ecological stressors. EPA's Guidelines for Ecological Risk Assessment (U.S. EPA, 1998) attempt to incorporate these biological characteristics and provide guidelines for conducting risk assessments on nonindigenous species.

The case studies presented in this chapter did not intentionally follow the EPA process (except for the EPA recombinant rhizobia assessment). Yet each case study follows the same logical sequences and steps outlined in the 1998 EPA document and provides examples of how analyses can be done on nonindigenous species.

4.2.3. Federal Agencies Involved in Nonindigenous Species Risk Issues

A number of Federal agencies are involved in issues surrounding nonindigenous species. These include, but are not limited to, the U.S. Department of Agriculture, Animal and Plant Health Inspection Service; U.S. Department of the Interior, Fish and Wildlife Service; Biological Resource Division, U.S. Department of Commerce (NOAA); U.S. Department of Defense; EPA; and NASA. A number of Federal and State agencies periodically or continually conduct nonindigenous species risk assessments of varying levels of detail and sophistication for various reasons in support of their primary missions.

Federal and State governments presently share responsibilities for issues concerning the introductions of plants, animals, and their diseases. At present the Federal effort is primarily a patchwork of laws, regulations, and policies scattered among several agencies. Most of these policies address nonindigenous species peripherally; others focus more narrowly on specific problems such as the introduction of crop pests. The need for a unifying national policy on nonindigenous species is generally acknowledged. However, the development of such a policy is impeded by historical divisions within and among government agencies and pressure from outside user groups and constituencies.

4.3. DISCUSSION ON THE STATE OF THE PRACTICE

The strength of using risk assessment to evaluate nonindigenous species is that it provides a framework for taking the available information and placing it into a format that can be used and understood by policy makers for making risk management decisions. The weakness of risk analysis for nonindigenous species rests with the specific problems associated with predicting the outcome of a newly established species in a new environment. The most serious problem is the lack of information on specific organisms and our current state of understanding on how an ecosystem functions.

Even complete life-history studies of a nonindigenous species do not guarantee that managers can predict the impact that the species will have when introduced (although, admittedly, good scientific information helps). The reason is that the complexity of the interaction between the organism and a new environment is so great that current predictive models do not work with enough reasonable regularity to help decision makers. Indeed, there is mounting evidence that normal linear predictive models rarely capture what occurs in a self-actualized criticality or chaotic-based ecosystem.

It is important to note that the difficulty surrounding the evaluation of an exotic biological stressor does not negate the need for management decisions to be made. It also is important to realize that because information derived from scientific methods is probabilistic and provisional, not absolute, we will never be free of uncertainty. The risk assessment, if properly designed, should allow new and innovative predictive models to be incorporated. The degree of uncertainty surrounding the introduction of nonindigenous organisms only increases the need for careful, unbiased risk assessments before making a decision for or against an introduction. It is imperative that a risk assessment honestly communicate its predictive limitations along with its strengths to policy makers.

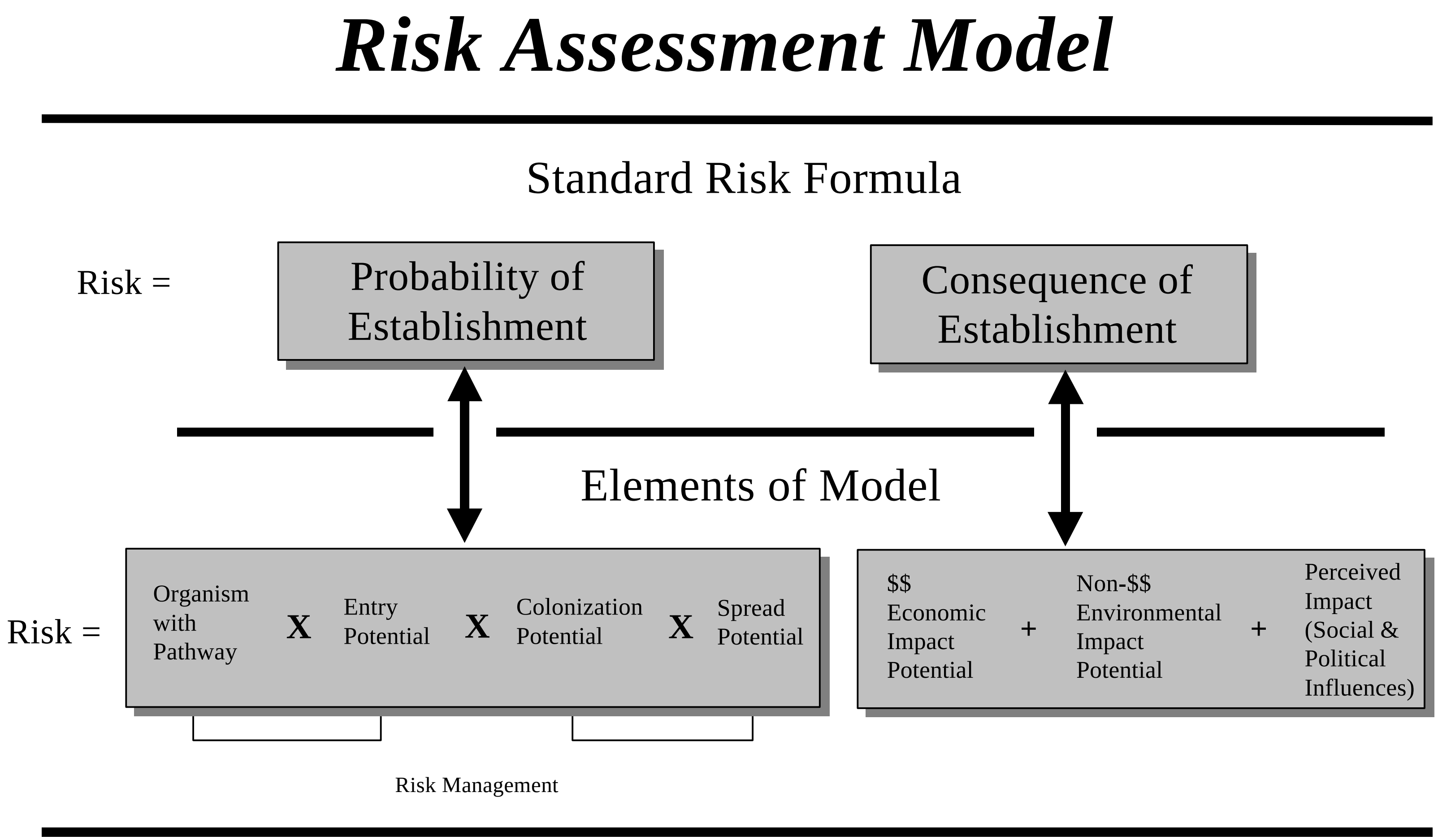
The connection between risk assessment and risk management must be present for the risk assessment to be relevant to the needs of the risk managers. All three case studies in this chapter showed how the risk assessment (assessors) can be connected to the risk managers. The need for this type of initial bond (communication) between the assessors and the managers is recommended in the final report of the Presidential/Congressional Commission on Risk Assessment and Risk Management (1997).

4.4. CASE STUDIES

4.4.1. Risk Assessment on Black Carp (Pisces: Cyprinidae)

The black carp risk assessment (Nico and Williams, 1996) was initiated to test the Generic Nonindigenous Aquatic Organisms Risk Analysis Review Process (RAM, 1996). This "review process" was developed by the Risk Assessment and Management (RAM) Committee to meet the risk analysis needs of the Aquatic Nuisance Prevention and Control Act of 1990. The committee represented a number of government agencies, potentially impacted industries, and special interest groups. The review process as a risk assessment tool was designed to evaluate recently established nonindigenous organisms, evaluate nonindigenous organisms proposed for deliberate introduction, and evaluate the risk associated with individual pathways (e.g., ballast water, aquaculture, aquarium trade, fish stocking). As a risk management tool, the review process was designed to reduce the probability of unintentional introductions and reduce the risk associated with intentional introductions (RAM, 1996).

The nonindigenous species risk assessment process used by the review process is outlined in Figure 4-1. The assessment is divided into probability of establishment and consequences of



- For model simplification, the various elements are depicted as being independent of one another.
- The order of the elements in the model does not necessarily reflect the order of calculation.

Figure 4-1. Risk assessment model from the Report to the Aquatic Nuisance Species Task Force.

Source: Adapted from RAM, 1996.

establishment. Biologic, economic, and other pertinent information is organized under the seven elements. Each of the elements is assigned a risk rating and an uncertainty rating based on the information gathered under the element. The ratings for each element are then combined to provide an overall rating for the nonindigenous species being evaluated.

The black carp (*Mylopharyngodon piceus*) was chosen as a test organism for the review process because it demonstrated: (1) a real issue in which the potential for positive gain (biological control of yellow grub and zebra mussel) has to be balanced with the potential of becoming established and causing economic and/or environmental damage in a new environment; (2) a real issue in which political, economic, and environmental concerns were already present (an assessment process must be able to withstand issues that are controversial); and (3) a situation in which there still exists time to correctly manage this issue to the benefit of the American people (the assessment would not have been done in vain).

The black carp is native to eastern Asia. Although it is one of several commercially important carp species in China, some aspects of its natural history, such as details of its reproduction in natural conditions, are poorly known. Most of the data on black carp natural history are studies originally published in Russia and China.

Sections 4.3.1.1 and 4.3.1.2 give a summary of the black carp assessment, which follows the risk model provided in Figure 4-1.

4.4.1.1. *Probability of Establishment*

1. Estimate probability of the exotic organism being on, with, or in the pathway: *High—very certain*. This species is already present in the United States. The pathway is dependent on human transport.

2. Estimate probability of the organism surviving in transit: *High—very certain*. The black carp is present, and survival in transit has been proved on at least several occasions.

3. Estimate probability of the organism successfully colonizing and maintaining a population where introduced: *Medium—reasonably certain*. Appropriate habitats and climate are found throughout most of the United States (i.e., large rivers and canals). Preferred food (i.e., aquatic snails and mussels) is locally abundant. The black carp became established after it was introduced to several localities in Asia (e.g., Japan, possibly northern Vietnam), including at least one water body in the former Soviet Union (Kara Kum Canal). In addition, the grass carp, a closely related species from Asia with similar spawning habitat requirements, has naturally reproducing populations in open waters of the United States.

4. Estimate probability of the organism to spread beyond the colonized area: *High—reasonably certain*. Appropriate habitats (i.e., large lowland rivers and canals) and climate are available throughout most of the United States. Preferred foods (i.e., aquatic snails and

mussels) are locally abundant in most U.S. rivers. The black carp is closely related to another east Asian cyprinid, the grass carp (*Ctenopharyngodon idella*); the native distributions of these two species are nearly identical, and their reproductive requirements appear to be very similar. As such, if the black carp colonizes open water sites within the United States, the species would likely spread beyond colonized areas, as has been the case with the grass carp. The grass carp was first introduced into the United States (Alabama and Arkansas) in 1963 and now occurs in more than 45 States.

Unless intentionally or incidentally spread into other areas by humans, black carp spread in the United States would be expected to be limited to those river basins where introduced. Major river basins in the United States that appear to provide appropriate habitat include the Mississippi, the Snake, the Sacramento-San Joaquin, and the Colorado, among others. However, if the black carp is salt tolerant, there is a risk that carp could spread along coastal waters into adjacent basins or drainages. In a laboratory setting, the closely related grass carp has been shown to survive up to 24 days in 10.5 parts per thousand salinities. Additionally, because of their similarity in appearance to grass carp, there is potential that black carp will be incorrectly identified as grass carp and be unintentionally introduced to some areas. Based on climate, black carp might be expected to occur over at least most of the continental United States as well as Hawaii.

4.4.1.2. *Consequences of Establishment*

5. Estimate economic impact if established: *Low—moderately certain.* Possible costs incurred from introducing black carp include: (1) reduction in the numbers and kinds of native mussels (many of which are important to the freshwater mussel industry); (2) competition with native fishes; (3) competition with waterfowl and other vertebrates that utilize mollusks for food; and (4) introduction of a probable carrier of parasites and diseases that utilize mussels as an intermediate host (while the carrier frequently remains immune from the effects of the disease itself).

The low rating is justified because none of the negative impacts described above would strongly affect the U.S. economy. The domestic freshwater mussel industry is likely to be most affected, but the extent of the damage is unclear. It is unlikely that black carp would be capable of feeding on the adults of the majority of the species utilized by the mussel industry; however, black carp would probably be able to take juveniles of these species.

6. Estimate environmental impact if established: *High—very certain*. It is highly likely that the black carp would negatively impact native aquatic communities by feeding on and reducing populations of native mussels and snails. The black carp is known to feed on mussels that are similar in shape and size to some native mussels of the United States. The United States has a high diversity of gastropods and bivalves, and many of these are endemic to relatively small

regions of the country. For instance, the black carp would potentially threaten many of the imperiled mussels currently on the brink of extinction. Of the 297 native freshwater mussels, 213 taxa (71.7%) are considered endangered, threatened, or of special concern. There also exists potential that the black carp would directly compete for food (i.e., snails) with several other fish species (e.g., certain catfishes, sunfishes, and suckers, freshwater drum), as well as certain birds and mammals, including some native species listed as threatened or endangered. Because the black carp shows a preference for snails as food, there is potential for impacting stream communities where snails play an important role as a grazer of attached algae. Black carp may directly and indirectly reduce aquatic insects.

7. Estimate impact from social and/or political influences: *Medium—moderately certain*. Certain groups and industries in the United States support the introduction of the black carp, including many fish farmers and also industries that have a problem with zebra mussels and perceive black carp as a potential solution.

Those against introducing the black carp include various environmental groups and persons involved with the mussel and freshwater pearl industries. The American Fisheries Society recently passed a resolution asking governmental agencies to strictly prohibit the sale, possession, and distribution of black carp, largely in part because of the potential to harm native mussel fauna.

The overall rating of *unacceptable risk* was recommended by the assessor and agreed to by the managers for uncontrolled releases of black carp. The assessors recommended that its establishment in North American native aquatic environments should be prevented. However, the assessors did conclude that sterile (triploid) black carp kept under a strict quality assurance program could be used (introduced) for specific uses.

In this study, the risk communication between the risk managers and the risk assessors was provided (as outlined in the review process) as specific management questions that were submitted to the risk assessors before the assessment was started. These questions contained the specific problems that the managers hoped the assessment would answer, but not what they wished the outcome of the assessment to show. In this way the assessment was kept policy relevant without becoming policy driven. Suggestions and processes for reducing the risk of nonindigenous species (risk management) are covered in the review process but were beyond the purview of the black carp test case.

4.4.2. Risk Assessment for the Release of Recombinant Rhizobia at a Small-Scale Agricultural Field Site

The case study "Ecological Risk Assessment Case Study: Risk Assessment for the Release of Recombinant Rhizobia at a Small-Scale Agricultural Field Site" (McClung and Sayre, 1993) was not written in response to a particular problem, but was written at the request of EPA's Risk Assessment Forum to test the utility of EPA's Framework for Ecological Risk Assessment (U.S. EPA, 1992) with biological stressors, specifically, genetically engineered microorganisms. Although the framework was written for chemical and physical stressors, the Risk Assessment Forum was interested in identifying the shortcomings of the framework for biological stressors.

Rhizobia, a general term for various species of the genus Rhizobium (and because of a recent taxonomic revision, also Sinorhizobium), are gram-negative, motile, rod-shaped, aerobic bacteria that infect legume roots, forming a symbiotic relationship with the plant. The bacteria fix atmospheric nitrogen, providing an inorganic nitrogen form, ammonium, usable by the plant in exchange for energy from the plant in the form of photosynthate, specifically dicarboxylates. The parental strains were modified by insertion of various genes, including antibiotic resistance markers to allow for detection of these recombinants in the environment from indigenous rhizobia, and nif genes to enhance the nitrogen fixation capability of the microorganism.

In 1988 and 1989, EPA received voluntary premanufacture notifications (PMNs) for proposed small-scale field testing in 1989 of various recombinant strains of *Rhizobium meliloti*. These "intergeneric" microorganisms were reviewed using typical procedures within the Office of Pollution Prevention and Toxics' Biotechnology Program. For a PMN submission under Section 5 of the Toxic Substances Control Act (TSCA) Section 5, an integrated risk assessment is developed. Various assessments are written in support of a final risk assessment, including a human health hazard assessment, an ecological hazard assessment, a construct analysis, a chemistry report, an engineering/worker exposure report, and an environmental exposure assessment. The risk is evaluated using the typical EPA paradigm Risk = Hazard × Exposure. Since TSCA is a risk-versus-benefit statute, the benefits to society of use of a microorganism are weighed into the final risk management decision. If a finding of "no unreasonable risk to human health or the environment" is made, then the Agency takes no regulatory action. However, if there is sufficient information to show an unreasonable risk, or if there is insufficient information to determine that the risks are reasonable, then the Agency can prohibit or restrict the use of a microorganism.

Since the case study followed the Risk Assessment Forum framework (U.S. EPA, 1992), the summary that follows is given in the same general format.

4.4.2.1. *Problem Formulation*

The case study focused on determining potential adverse effects of conducting small-scale field trials in 1989 with recombinant rhizobia. The stressor was genetically engineered rhizobial strains that could result in two types of effects: biological effects (e.g., altered alfalfa growth, altered growth of other nontarget legumes, displacement of indigenous species, gene transfer) and chemical effects (production of toxins, detrimental metabolites, overproduction of nitrate). Characterization of the recipient and donor microorganisms was a critical component for the risk assessment.

The four recombinant rhizobia reviewed were strains made by the insertion of a gene encoding for resistance to the antibiotics streptomycin and spectinomycin, which allowed the recombinants to be differentiated from their parental strains in both the laboratory and the environment. Additional nif genes, which encode for the enzyme nitrogenase, also were inserted into one strain to enhance the nitrogen fixation capacity of the rhizobial strain.

The ecosystem potentially at risk was the surrounding agroecosystem in Dane County, WI. Potential biotic components of the agroecosystem of concern were target and nontarget legumes (including weedy crop legumes and noncrop legumes), native rhizobia, and bacterial pathogens that could acquire the antibiotic resistance genes from the recombinant rhizobia. The primary concern was the area surrounding the field plots, with lessening concern for areas farther removed from the field site.

A number of assessment endpoints were identified: (1) decreased alfalfa growth, (2) decreased growth of legumes outside the typical nodulation/cross-inoculation group, (3) decreased growth of nonlegume crops, (4) unanticipated effects of introduced DNA sequences, (5) effects of introduced DNA on recipient DNA at the insertion site, (6) unanticipated effects of recipient microorganisms, (7) effects of antibiotic resistance genes, (8) competitive displacement of native rhizobia if coupled with hazards listed in 1-3 or 9-10, (9) increased/decreased growth of sweet clover, (10) increased/decreased growth of fenugreek, (11) effects of coumarin on cattle, and (12) effects on the nitrogen cycle.

Predictive information on assessment endpoints 1 through 7 was used in the risk assessment. The only assessment endpoints to be monitored during the field trials were 1 and 8—the effects on alfalfa yield and the competitiveness of the introduced recombinant strains for alfalfa nodulation, respectively.

4.4.2.2. *Analysis: Characterization of Exposure*

The number of microorganisms to be released in the 1989 field trials was on the order of 10^{12} cells for each strain applied through in-furrow spraying. However, there was uncertainty regarding exposure over time because of the potential for microbial reproduction and transport.

Survival in the soil and root nodules, vertical and horizontal movement through soil, and aerial dispersion warranted consideration. The ability to detect the recombinant microorganisms in the environment created uncertainty because of the lack of sophisticated techniques available at the time of the field studies. Laboratory studies showed a 1-log decline in numbers over a 4-week period. However, literature data had shown extended survival of rhizobia in soils, particularly in the presence of a suitable host plant. The fact that alfalfa is a perennial crop suggested that the recombinant rhizobia could potentially survive for years once released in the environment.

The field trials were intended for a 2-year period. Although literature data indicated limited movement of rhizobia in soils, there was potential for aerial dispersion during inoculation or through wind-blown soil particles, and there was also the potential for runoff from the field test site given heavy precipitation. The presence of nontarget legumes in the 14-acre test site area was evaluated before initiation of the field tests as another facet of the exposure characterization. It was assumed that there would be limited off-site migration of the recombinant rhizobia.

4.4.2.3. *Analysis: Characterization of Ecological Effects*

The primary effects data reviewed before the field test were greenhouse data on alfalfa yield resulting from nodulation with the recombinant rhizobia. With one exception of increased yield, greenhouse studies did not demonstrate any significant differences in nitrogen fixation as measured through alfalfa top growth. However, the greenhouse studies were of questionable utility. The data provided did not address ecological effects that would be of concern if there were substantial movement of the microorganisms off-site, such as:

- Increased competitiveness
- Increased nitrogen and, therefore, nitrate production in soils
- Alteration of host range
- Effects on nonleguminous plants
- Effects on other legumes, sweet clover, and fenugreek, which are also known to be nodulated by *R. melilottal*
- Spread of antibiotic resistance genes to other microbial populations.

4.4.2.4. *Risk Characterization*

The risk of conducting the small-scale field testing with the recombinant rhizobia was considered low. The case study did not evaluate several assessment endpoints because of the limited likelihood of off-site dispersal of the microorganisms. Even if dispersal had occurred, the small number of microorganisms applied may have precluded effective nodulation of other legumes in the ecosystem of interest. The assessment did not address various large-scale effects, such as effects on the nitrogen cycle or the spread of clinically important antibiotics, because this was a small-scale field test site that was expected to remain small scale. Both effects and fate data had elements of uncertainty resulting from the protocols used and extrapolation from laboratory and greenhouse studies to field situations. There was no information on the effects of the recombinant rhizobia on other legumes. Likewise, there were no data on the competitive ability of these rhizobial strains compared with native rhizobia. The ability of the monitoring techniques for the recombinant rhizobia also led to uncertainty.

4.4.2.5. *Risk Verification*

Data obtained from the small-scale field tests verified the risk assessment conducted for this PMN submission. As expected from knowledge of rhizobial behavior and greenhouse data, the recombinant rhizobia survived well in the rhizosphere of alfalfa plants. Field results did not show any increased competitiveness of the recombinant rhizobia as evaluated by nodule occupancy. As expected, there was little off-site movement of the strains observed in the various dispersal studies. In addition, as predicted from laboratory and greenhouse studies, the construct analysis, and the literature, there were no adverse effects on alfalfa growth with any of the rhizobial strains tested, nor were there any significant differences in alfalfa growth between the recombinant strains and their unmodified parental strains.

This case study followed the format of the ecological risk assessment framework, which has been extensively peer reviewed and tested with chemical and physical stressors. Although there were various shortcomings of the framework in relation to biological stressors—such as the lack of provision for survival, multiplication, and dispersal of both the microorganisms and the introduced genetic material—this case study should serve as a useful model for assessing the risks of future releases of genetically modified microorganisms. One strength of the case study was the existing body of knowledge on the effects of previous rhizobial inoculations with naturally occurring rhizobial strains. The practice of using rhizobial inoculants has a long history (nearly a century) of safe use. Another attribute of this case study is the risk verification portion, whereby it was possible to compare the outcome of the ecological risk assessment conducted using the framework with the in-house risk assessment done for the PMN submission, and to have the risk assessments validated by the data and results obtained during the field trials. The field data confirmed the predictions of the framework ecological risk assessment and the EPA PMN submission risk assessment.

4.4.3. Scenario Analysis for the Risk of Pine Shoot Beetle Outbreaks

The pine shoot beetle was discovered in North America near Cleveland, OH, in July 1992. At the time of the analysis (January 1995), it was known to be established in six States: Illinois, Indiana, Michigan, New York, Ohio, and Pennsylvania. It was expected to continue spreading naturally.

The pine shoot beetle is the most destructive bark beetle (Scolytidae) of pines in Eurasia, where it is a native pest. It can cause serious damage to the new growth of healthy trees as well as to weak and dying ones. Healthy trees are at risk when populations of the beetle are high. The beetle also may be an important vector of several diseases of pine. The current season's growth (shoots) of many species of pine serve as the primary hosts for feeding by adult beetles, while felled logs and downed trees are the primary breeding sites.

The pine shoot beetle has great potential to spread. Adults can fly 1 km, and the logs, rough-cut lumber, nursery stock, Christmas trees, and decorative foliage they infest are often transported long distances.

Infested counties were regulated under Federal and State quarantines. Logs of pine trees could be transported from infested counties to noninfested areas from July 1 through October 31 with no restriction (most beetles are assumed to be in the shoots during this time—normal logging practice would remove all branches from the logs before moving to the sawmill). From November 1 through June 30, logs must be fumigated or processed at the destination within 24 h of harvest (beetles are overwintering at the base of the tree during this time; the assumption is that beetles are destroyed during debarking/processing at the sawmill).

Early in 1994, the Michigan Department of Agriculture (MDA) proposed modifications to the current regulatory regime. The APHIS of USDA rejected the proposal, resulting in a continuing discourse with MDA, APHIS, and the USDA Forest Service about technical aspects of the proposal, options, and risk.

An analysis document was developed by APHIS to provide an assessment of the risks so that any decision regarding regulations will be sound. Scenario analysis was offered as a methodology to evaluate the variables contributing to the pest risk and to identify the options to mitigate the risk.

The product of this effort will provide the basis for evaluating and adjusting quarantine regulations.

4.4.3.1. *Assessment Summary*

A single expert meeting was organized to discuss scenarios and the evidence surrounding each event component. Five outside experts representing a range of experience and perspectives met with several APHIS staff members for 2½ days of discussion. Technical background information was provided to experts in advance of the meeting. The results (USDA, 1994) are summarized herein.

Figure 4-2 describes the combination of scenarios determined to be the pathways for possible new outbreaks. Each pathway was demonstrated individually with its respective data in the section of the document devoted to the analysis of the probability data. Probability estimates were developed by the expert group for each event for each scenario. The products of point estimates for each scenario have been calculated and added to the summary table. Evidence and reference materials used or provided as the basis for estimates were listed in an appendix.

In each scenario, the most likely probability in the sequence of events occurring was represented by a point estimate (mode value) and surrounded by an estimate of the lowest and highest probability in a triangular distribution. Experts were encouraged to estimate a range to ensure that the actual probability lay within the area of the curve defined by the estimates. A point estimate alone was used when the evidence indicated a very high degree of certainty. Estimates and continuing calculations of probability were terminated when any event resulted in the elimination of the pest risk. The estimates were based solely on Michigan data; however, the probability estimates developed from the data are believed to be generally representative of locations in the North Central and Northeast United States above 40° north latitude.

By combining the curves for each event in a scenario pathway, an overall estimate of the risk and associated uncertainty was developed for scenarios describing the situation(s) as they would be without the addition of mitigation. This facilitated the identification of high-risk scenarios and events. It also provided the background for evaluating the application and value of mitigation schemes applied to specific scenarios and events.

Each scenario (A, B, C, and D) was analyzed according to seasons corresponding with the insect's activities (summer, fall, winter, early spring, and late spring). This creates a total of 20 subscenarios. However, the summer subscenarios were determined by experts to have a negligible risk after the first event because insects would be feeding in shoots and therefore would not be associated with delimbed logs during this period. Eliminating the summer subscenarios brings the total number of subscenarios to 16.

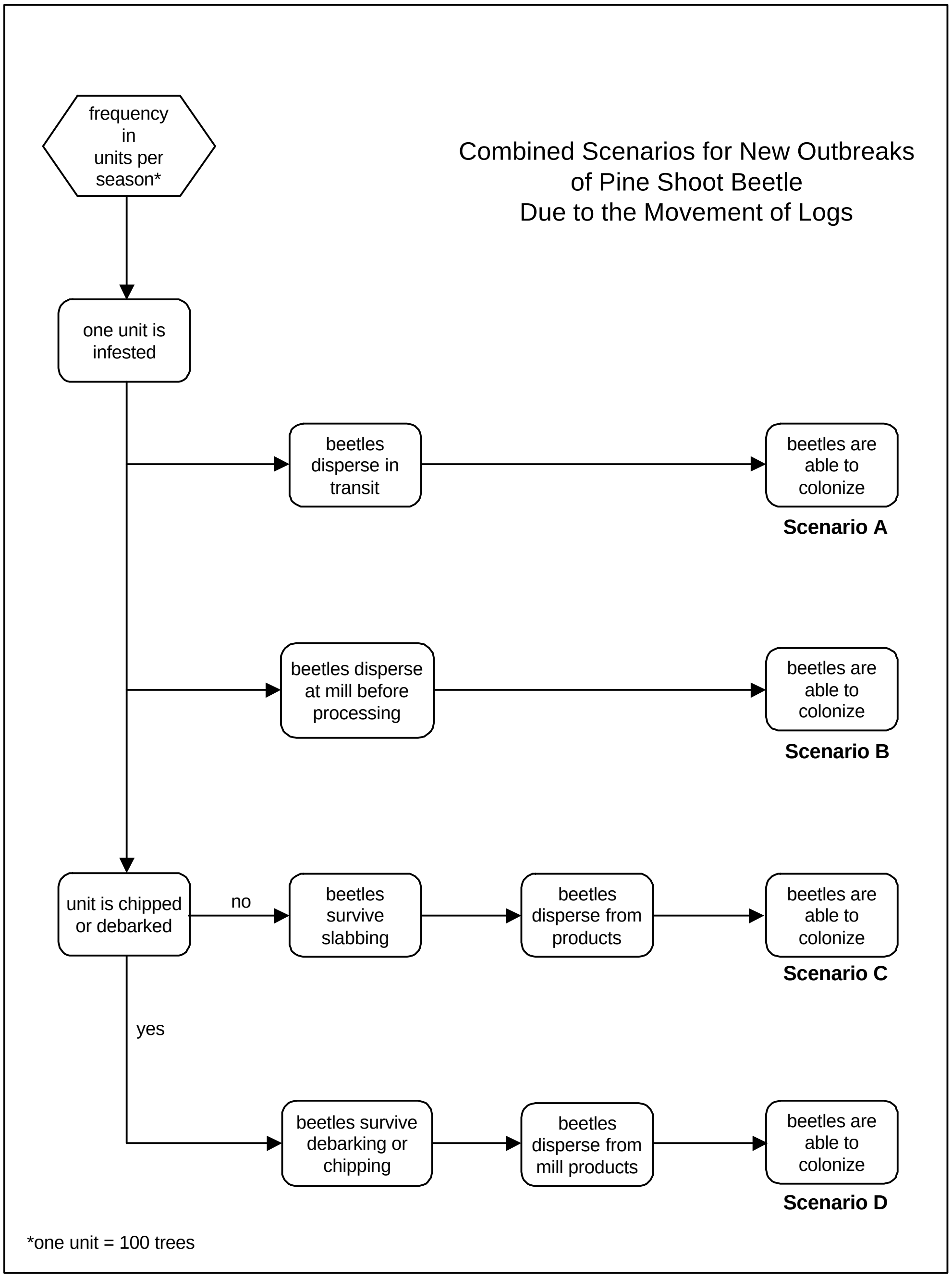


Figure 4-2. Combined scenarios for new outbreaks of pine shoot beetle due to the movement of logs.

Computer simulation using specially designed software (@ Risk by Palisade Software, Inc.) was used to graphically represent the distributions for each event and to calculate the product of all events for a scenario. Two types of curves were generated using Latin hypercube sampling and 3,000 to 9,000 iterations (trials with random numbers). One curve is roughly "bell-shaped" and demonstrates the distribution of probability across the range of values defined by the experts. The other curve is S-shaped and demonstrates the cumulative probability from 0% to 100%. The endpoints—the frequency of outbreaks by season and year—are given in Table 4-1 for the 16 subscenarios.

4.4.3.2. *Risk Management Summary*

After the expert group completed the assessment, a list of 10 potential risk management options was developed. The list included options such as having no restrictions on logs without bark to allowing movement from regulated areas after fumigation to allowing the movement after certain dates. Then the group discussed a list of potential treatment measures. These included fumigation, debarking, insecticide spray, total tree utilization, butt-cutting, high stumping, and

Table 4-1. Frequency of outbreaks of the pine shoot beetle and years between outbreaks

Dispersal from:		**New outbreaks per year**	**Years between outbreaks**
Scenario A *Transit*	mean	0.00369	271
	mode	0.000905	1,110
	95% limit	0.00949	105
Scenario B *Mill*	mean	0.00379	264
	mode	0.000698	1,430
	95% limit	0.00995	101
Scenario C *Slabwood*	mean	4.63	0.22
	mode	0.884	1.13
	95% limit	11.8	0.08
Scenario D *Mill by-products*	mean	0.0000103	97,300
	mode	0.00000125	802,000
	95% limit	0.0000302	33,100
All scenarios by season	mean	4.64	0.216
	mode	0.885	1.13
	95% limit	11.8	0.0846

others. Finally, fumigation options were identified that would allow the safe movement of logs and lumber with bark from the regulated area for four time periods. The options included fumigation, movement to an approved facility, and harvesting time limitations. Restrictions on logs moved between February 16 and June 30 (early and late spring periods) were the most restrictive. Restrictions on logs moved between July 1 and September 30 were the least restrictive. This corresponded with the risk identified in the assessment section. The following advantages were identified in the process used for the pine shoot beetle assessment:

- The use of scenario trees aids the assessor and readers in identifying and understanding the events within a pathway that lead to an unwanted consequence.

- Convening an expert group meeting for the development of estimates for determining risk was beneficial. The method used here was a modification of the expert information approach developed by Stan Kaplan (1992). Statistical and nonstatistical information relevant to the parameter was reviewed and discussed by the participants. Then low, high, and point (most likely) estimates were established for each event. Thus, the uncertainties of the estimates are captured in the curve (probability distribution) developed by the group. A high narrow curve indicates a large degree of certainty (confidence); a wide low curve indicates a lack of confidence.

- The resulting probability distribution from the calculations documented the amount of certainty in a process matter. In addition, the quantitative process allowed the risk managers to understand the great differences in risk between a low-risk and high-risk scenario. For example, 1 of the 16 scenarios represented more than 65% of the risk while the 12 lowest risk scenarios combined represented only 0.2% of the risk. Giving the one scenario a qualitative value of high risk and the 12 others a value of low risk would not convey the differences in magnitude.

4.5. NEXT STEPS

These recommendations are intended for the Federal and State agencies that periodically or continually conduct nonindigenous species risk assessments to support their primary missions.

- Improve the science surrounding nonindigenous species to achieve a better understanding of why some species are more likely to establish and become pests.

- Conduct retrospective evaluations of nonindigenous organism risk assessments to identify opportunities for improvement of existing processes and methods and to help determine which approaches work the best under what circumstances.

- Improve Federal interagency cooperation to help reduce redundancy and focus limited resources.

- Enhance international cooperation. Global management strategies will be necessary to address many nonindigenous species problems. Participation in existing international organizations for plant and animal protection, environmental protection, and ballast water management should be encouraged, and new opportunities for cooperation should be pursued.

- Improve awareness of nonindigenous species issues by the public and potential stakeholders through communication and education. Ensure that interested parties and concerned individuals are involved in risk assessment planning and in the management of nonindigenous species.

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5. CERCLA

5.1. SUMMARY

Ecological risk assessments under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) are retrospective evaluations of the effects of contamination in a given area. They provide baseline information on whether a clean-up should be considered for ecological reasons, and risk assessments are used in the evaluation of remedial alternatives. Each of the three case studies follows the EPA framework, and they present and discuss the three phases of ecological risk assessment.

Three case studies are presented in this chapter. The Linden Chemicals and Plastics site in Georgia was contaminated with mercury and polychlorinated biphenyls (PCBs). The site was evaluated for its impact on selected mammals and birds exposed to the contaminants through a saltmarsh. Tissue samples were collected from selected specimens at the contaminated site and a reference site. A food web approach was used and compared with toxicity values found in the literature. Substantial threat concentrations and potential risk concentrations were identified.

The United Heckathorn site presents an assessment of DDT contamination of a section of San Francisco Bay. Benthic community structure, fish tissue levels, sediment toxicity tests, and food web models were conducted in the analysis phase of the assessment. Areas of sediment were identified for remediation to reduce the risk to birds and fish to acceptable levels (i.e., bulk sediment concentrations of 1.9 mg/kg DDT at 1.9% total organic carbon).

The Metal Bank of America site was located on the Delaware River, and PCBs were the primary contaminant. The protection of the shortnose sturgeon, a designated endangered species, and other fish species were assessment endpoints. Tissue levels of representative fish collected at the site were compared with literature values. The risk characterization determined that there was potential risk to fish reproduction.

Risk managers are required to protect human health and the environment and to comply with applicable, relevant, and appropriate requirements. They also balance the risk and proposed mitigation methods with various economic, societal, technical, and political concerns discussed in this chapter.

5.2. INTRODUCTION

The fundamental purpose of performing an ecological risk assessment at Superfund sites is to determine if releases or potential releases of hazardous substances from the site have resulted in or are likely to result in unacceptable adverse effects on ecological receptors. The goal of Superfund response actions is to prevent effects from occurring or, if effects have occurred, to implement a remedy that will provide adequate protection of the ecological resources in a cost-effective manner that also meets any appropriate Federal or State laws.

Ecological risk assessment data are used for:

- Characterizing baseline risk to determine whether a cleanup should be considered,

- Deriving specific contaminant concentrations that provide adequate protection from unacceptable risks,

- Evaluating the remedial alternatives for potential effectiveness and potential risks, and

- Providing baseline information that can be followed with monitoring to document that the remedy is effective at reducing risk.

Table 5-1 presents the use of ecological data in Records of Decision (RODs) in 1995. According to Section 104(a)(1) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), whenever there is a release or a substantial threat of a release of a hazardous substance into the environment, EPA is authorized to take whatever action is deemed appropriate to protect the environment, as long as the action is consistent with the National Contingency Plan (NCP). EPA uses the information from the risk assessment in its decision-making process.

The NCP requires that a baseline risk assessment be conducted by the lead agency during the remedial investigation/feasibility study in order to "characterize the current and potential threats to human health and the environment" (Section 300.430[d][4]). Any remedy selected by EPA must be protective of the environment and human health. It must also comply with any enforceable Federal or State standards or criteria that apply to the site. In addition, the NCP requires that certain balancing criteria be considered: (1) long-term effectiveness and permanence of the response; (2) reduction of toxicity, mobility, or volume of the waste through treatment; (3) short-term effectiveness; (4) implementability; and (5) cost. Two modifying criteria also must be considered: State acceptance and community acceptance.

Section 300.430(e)(9)(iii)(A) of the NCP states, "Alternatives shall be assessed to determine whether they can adequately protect human health and the environment, in both the short- and long-term, from unacceptable risks posed by hazardous substances."

Table 5-1. Use of ecological data in Records of Decision (RODs) in 1995

Explanation	Total number	Percentage of total RODs
Number of RODs with ecological risk assessments	113	60%
Number of RODs where remedial action based at least partially on ecological risk	52	46%
Number of RODs where population/ community study performed	24	21%
Number of RODs where modeling performed	25	22%
Number of RODs where literature values used	50	44%
Number of RODs where ambient water criteria used	19	17%
Number of RODs where NOAA[a] sediment values used	11	10%
Number of RODs where site-specific toxicity tests performed	14	12%
Number of RODs where tissue sampling performed	10	9%

[a]NOAA = National Oceanic and Atmospheric Administration.

Risk assessments should be designed to determine a threshold media concentration that will provide adequate protection of important ecological resources. This requires substantial discussion between the risk assessor and the risk manager before sampling to make sure the information needed to make these decisions is collected. Many remedial alternatives have short-term adverse consequences for the environment because of resulting physical disruption of the ecosystem.

5.3. RISK MANAGEMENT

The Superfund program currently has few written policies or guidances that explicitly explain how to make reasoned ecological risk management decisions. Often the decision maker must rely on the guidance given in the NCP. Unlike human health risk assessments, which have quantifiable risk goals that define levels of acceptable risk to one species (e.g., to reduce human cancer risks to levels below 1 in 10,000), quantifiable ecological risk assessment, goals have not been established by the Agency. The NCP states only, "Alternatives shall be assessed to determine whether they can adequately protect human health and the environment, in both the short- and long-term, from unacceptable risks posed by hazardous substances" (Section 300.430[e][9][iii][A]). This lack of a simple and easily articulated cleanup goal makes the selection of an appropriate remedy that is protective of the environment and meets the other eight NCP criteria problematic. In the Agency's recent Five-Year Strategic Plan, the Administrator stated that one of EPA's goals is to achieve "healthy, sustainable ecosystems" (U.S. EPA, 1994). Superfund risk managers and risk assessors should work together to translate this overarching goal into site-specific goals and objectives.

Superfund decision makers must consider nine criteria when selecting a response action that is appropriate for the site:

- Overall protection of human health and the environment
- Compliance with applicable, relevant, and appropriate requirements (ARARs)
- Long-term effectiveness and permanence
- Reduction of toxicity, mobility, or volume through treatment
- Short-term effectiveness
- Implementability
- Cost
- State acceptance
- Community acceptance.

The first two criteria are thresholds that must be met at every site (though the ARARs can be waived under certain circumstances), the next five are balancing criteria, and the last two are modifying criteria. The three criteria usually most important to the ecological risk manager are protection, long-term effectiveness, and short-term effectiveness.

5.4. CASE STUDIES AND EXAMPLES

5.4.1. Linden Chemicals and Plastics Wildlife Assessment

The Linden Chemicals and Plastics (LCP) site is located in Brunswick, GA. Among other operations, LCP operated a chlor-alkali plant from 1955 through the closing of the facility. Graphite electrodes were impregnated with polychlorinated biphenyls (PCBs) (specifically Aroclor 1268). The site is adjacent to a saltmarsh system that encompasses 550 acres.

To support EPA Removal Program objectives, the LCP wildlife assessment conformed to the EPA process for designing and conducting ecological risk assessments (U.S. EPA, 1997). Bulk chemistry, toxicity tests, population and community evaluations, and contaminant accumulation data were used in exposure models to evaluate ecological risks at this site. Sampling locations were based on the ability to collect not only target organisms but also the organisms at targeted contaminant exposure levels.

5.4.1.1. *Problem Formulation*

Information collected at the site indicated that PCBs and base, neutral, and acid-extractable compounds and metals (particularly mercury and lead) were the contaminants of concern (COCs). The concentrations of these compounds were compared with benchmark criteria (i.e., no-effect levels) to determine if further investigation was necessary. This procedure is defined as a preliminary risk assessment. Any contaminant in which the resultant quotient was less than 1 was discontinued from further review. If the quotient was greater than 1 (indicating a potential for risk), the contaminant was retained for further review and evaluated using food chain accumulation models.

Although multiple COCs were identified, this case study addresses only mercury and PCBs. To determine the effects of these contaminants on biota, it is necessary to understand the mechanisms of toxicity of the chemicals and the systems that they affect.

5.4.1.2. *Hazard Characterization*

The objective of an exposure assessment is to determine the pathways and media through which receptors may be exposed to site contaminants. Exposure pathways are dependent on the habitats and receptors present on site, the extent and magnitude of contamination, and the environmental fate and transport of the COCs.

COCs present in forage and prey species could cause toxicity via ingestion in higher trophic level organisms. In addition to exposure via consumption of contaminated forage, ecological receptors may be exposed through incidental water and soil/sediment ingestion or through direct contact. The exposure pathways that were evaluated in this risk assessment were the ingestion of prey, the incidental ingestion of soil/sediment, and direct contact.

5.4.1.3. *Assessment Endpoints and Testable Hypotheses*

Three assessment endpoints selected for evaluation were:

- Protection of long-term health and reproductive capacity of omnivorous mammal species that utilize the marsh.
- Protection of long-term health and reproductive capacity of piscivorous (marine and terrestrial) mammal species that utilize the marsh/river system.
- Protection of long-term health and reproductive capacity of avian species that utilize the marsh and Purvis Creek.

The specific risk questions based on the assessment endpoints were as follows:

- Are levels of site contaminants in water, sediment, and biota sufficient to result in a dose that could cause adverse effects on the long-term health and/or recruitment of omnivorous mammal species that utilize the marsh?
- Are levels of site contaminants in water, sediment, and biota sufficient to result in a dose that could cause adverse effects on the long-term health and/or recruitment of marine or terrestrial piscivorous mammal species that utilize the marsh/river system?
- Are levels of site contaminants in water, sediment, and biota sufficient to result in a dose that could cause adverse effects on the long-term health and/or recruitment of passerine birds that utilize the marsh and Purvis Creek?
- Are levels of site contaminants in water, sediment, and biota sufficient to result in a dose that could cause adverse effects on the long-term health and/or recruitment of piscivorous/benthic organism-feeding birds that utilize the marsh and Purvis Creek?

5.4.1.4. *Conceptual Model*

The conceptual model was designed to determine the following: source release to marsh sediment and water; exposure of forage to contaminated water and sediment; and exposure of the assessment endpoints through ingestion of contaminated forage, incidental ingestion of contaminated sediment, and ingestion of contaminated water. The otter was selected as an endpoint because it ingests aquatic biota, sediment, and water; the raccoon was selected because it ingests aquatic biota and water; and the clapper rail (an avian species that utilizes the marsh and Purvis Creek) was selected because it ingests aquatic biota, sediment, and water.

The protection of long-term health and reproductive capacity of mammal species that use the marsh was determined to be an assessment endpoint. Food chain accumulation models with hazard quotient (HQ) evaluations were selected to evaluate risk to mammals that use the marsh. The otter was selected as a measurement endpoint for piscivorous mammals and the raccoon as a measurement endpoint for omnivorous mammals. Appropriate forage species were identified for the above receptors, collected, and analyzed. Exposure of receptors to contaminants was quantified and compared with existing toxicity data for these species.

The protection of long-term health and reproductive capacity of avian species that utilize the marsh and Purvis Creek was also determined to be an assessment endpoint. Food chain accumulation models with HQ evaluations were selected to evaluate risk to avian species. The clapper rail was selected as a measurement endpoint for wading waterfowl. Clapper rails and appropriate forage species were collected for the exposure model and analyzed. Dietary exposure of receptors to contaminants was calculated and compared with existing toxicity data for avian species.

5.4.1.5. *Food Chain Model Assumptions*

This portion of the assessment concentrated on exposure to mercury and PCBs through food ingestion. The body burden concentration of mercury and PCBs in prey items collected at the site was used to evaluate exposures to receptor species.

The risk characterization was initiated by evaluating each of the measurement endpoints. For the assessment endpoints that had multiple measurement endpoints, an overall risk conclusion was determined by reviewing the multiple lines of evidence (referred to as a weight-of-evidence approach).

Three ecotoxicological benchmarks were used:

- No-observed-apparent-effects level (NOAEL)
- Low-observed-adverse-effects level (LOAEL)
- Acute benchmark, which is used to evaluate imminent ecological threats.

Because mercury is a reproductive, behavioral, and developmental toxin, mortality can occur depending on the form of mercury and the degree of exposure. The rate of mercury speciation and chemical conversion also may determine the toxicity. Conservative assumptions were made on the proportion of organomercury versus inorganic mercury.

5.4.1.6. *Sources of Uncertainty*

Identification of the sources and nature of uncertainty for an ecological risk assessment is critical for the appropriate utilization of the risk assessment in risk management decisions. Identifying uncertainty allows for certain decisions to be made confidently; that is, the risk assessment can confidently identify where there is no substantial ecological risk. However, there may be uncertainty as to what level of contamination would actually result in an adverse response. Risk calculations were based on conservative life-history values (e.g., the lowest body weight and the highest ingestion rates). The benchmarks (NOAEL, LOAEL, and acute) used to determine HQs were also the lowest values found in the literature. While there is uncertainty associated with each benchmark, a consistent process for selection has been used in its selection.

5.4.1.7. *Clapper Rail Tissue Evaluation*

In July 1995, seven clapper rails were collected from the south marsh, and in August 1995, seven clapper rails were collected from the reference area. Table 5-2 presents the results of the evaluations. Mean mercury concentrations in the liver tissue of birds collected on the site were 15.7 mg/kg versus 3.5 mg/kg from birds from the reference area.

Acute mortality was found to be associated with liver mercury concentrations ranging from 4.6 mg/kg to 91 mg/kg wet weight in white-tailed eagles (*Haliaaetus albicilla*) (Henriksson et al., 1966; Koeman et al., 1972; Oehme, 1981; Falandysz, 1986; and Falandysz et al., 1988). Captive-raised grackles (*Quiscalus quiscula*) displayed mortality at 54.5 mg/kg wet weight in liver, whereas red-winged blackbirds displayed mortality at mercury concentrations in liver of 126.5 mg/kg wet weight (Finley et al., 1979).

5.4.1.8. *Hazard Quotient Results*

The HQ calculations incorporate the life-history information on the modeled species. The species used for the HQ calculations were selected as conservative representatives of a trophic level/food chain exposure pathway related to the assessment endpoints.

5.4.1.8.1. *Raccoon*. For mercury, the raccoon food web model predicts an acute threat at an exposure point concentration of 90 mg/kg (HQ = 1.1). When a LOAEL toxicity benchmark is used, the model predicts a threat of adverse responses at a sediment concentration of 15 mg/kg

Table 5-2. Clapper rail mercury and PCB tissue levels

	Mean from site, mg/kg (dry weight)	Reference area, mg/kg (dry weight)
Mercury tissue levels		
Breast muscle	5.1	1.6
Liver	15.7	3.5
Remaining carcass	5.1	1.1
Feathers	11.3	3.6
PCB tissue levels		
Breast muscle	9.2	0.8
Liver	212.0	0.8
Remaining carcass	27.8	1.8

(HQ = 6.6). For PCBs, the raccoon model predicts an acute threat at a sediment exposure concentration of 70 mg/kg (HQ = 1.0). When a LOAEL toxicity benchmark is used, the model predicts the threat of an adverse response at a sediment concentration of 2.3 mg/kg (HQ = 1.0).

5.4.1.8.2. ***Otter.*** For mercury, the otter model predicts an acute threat at an exposure point concentration of 90 mg/kg (HQ = 1.4). When a LOAEL toxicity benchmark is used, the model predicts a threat of an adverse response at a concentration of 15 mg/kg (HQ = 6.6). For PCBs, the otter model predicts a threat of acute toxicity at an exposure point concentration of 70 mg/kg (HQ = 2.5). When a LOAEL toxicity benchmark is used, the otter model predicts the threat of adverse responses at a sediment concentration of 5.2 mg/kg (HQ = 1.1).

5.4.1.8.3. ***Clapper rail.*** For mercury, the clapper rail model does not suggest the threat of acute adverse responses at an exposure point concentration of 150 mg/kg. When a LOAEL toxicity benchmark is used, the model suggests that there is a threat of adverse responses above 15 mg/kg (HQ = 3.2). For PCBs, the clapper rail model suggests that there is neither an acute threat nor a LOAEL-based threat of adverse response at an exposure point concentration of 150 mg/kg.

5.4.1.9. *Risk Assessment Conclusions*

5.4.1.9.1. ***Protection of long-term health and reproductive capacity of omnivorous mammal species that utilize the marsh.*** Based on HQ calculations and LOAEL benchmarks, there is imminent and substantial threat at exposure point concentrations of 90 mg/kg mercury and/or 70 mg/kg PCBs. Potential risk exists at levels at least as low as 15 mg/kg mercury and 2 mg/kg PCBs.

5.4.1.9.2. ***Protection of long-term health and reproductive capacity of piscivorous mammal species that utilize the marsh/river system (both marine mammals and terrestrial mammals).*** Based on HQ concentrations and LOAEL benchmarks, there is imminent and substantial threat at exposure point concentrations of 30 mg/kg mercury and/or 66 mg/kg PCBs. Potential risk exists at levels as low as 2 mg/kg mercury and 5 mg/kg PCBs.

5.4.1.9.3. ***Protection of long-term health and reproductive capacity of avian species that utilize the marsh and Purvis Creek.*** Food chain exposure models using HQ calculations indicate that there is a substantial and imminent threat due to sediment mercury concentrations of 34 mg/kg and sediment PCB concentrations of 56 mg/kg. LOAEL benchmarks indicate a risk at 90 mg/kg mercury and no potential risk based on PCB exposure. A comparison of body burden levels in clapper rails to literature values indicates that there is no risk due to mercury; however, there is substantial risk due to PCBs. In conclusion, based on the food chain accumulation models for clapper rail, it appears that there is imminent and substantial threat to at least one species at exposure point concentrations of 56 mg/kg PCBs and 34 mg/kg mercury (based on the food chain accumulation models calculated for clapper rails). In addition, the LOAEL benchmarks indicate that potential risk exists at 90 mg/kg mercury and that no potential risk is associated with PCBs.

5.4.2. United Heckathorn Assessment

5.4.2.1. *Site History and Background*

The United Heckathorn site has been a major source of DDT in San Francisco Bay since 1947, when a pesticide blending and packaging plant began operations. Although the pesticide blending and packaging operations ended in 1966, DDT accumulations in mussels near the site remain among the highest detected in the California Mussel Watch program. The site is located on the eastern shoreline of the central bay in the city of Richmond and includes Lauritzen Channel, Parr Canal, the Santa Fe Channel, and Richmond Inner Harbor. Sediments in the channels, harbor, and soils around the facility are contaminated with DDT, dieldrin, and other persistent chlorinated pesticides. An ecological risk assessment was completed for the site in 1994 by EPA’s Environmental Research Laboratory in Newport, OR (Lee et al., 1994).

5.4.2.2. *Problem Formulation and Conceptual Model*

Central San Francisco Bay provides habitat for many birds, fishes, and invertebrates. Aquatic habitats closest to the site include areas of soft bottom with armored shoreline used by anchovy, surfperch, starry flounder and English sole, herring, gobies, and other marine fish. Brooks Island lies at the southern end of the inner harbor, which is vegetated and surrounded by mudflats and patches of eelgrass that are used by Pacific herring. The open water channels near the site also are used by marine birds and harbor seals.

Contaminants of greatest concern include dieldrin and the DDT metabolites, which are both readily adsorbed to sediment particles. The loading of pesticides into vessels adjacent to the site resulted in direct discharge to the channels, where sediments are now highly contaminated. The pesticides also are present in surface water and pore water and are accumulating in biota at the site. DDT is associated with reproductive impacts in fish-eating birds. DDT metabolites and dieldrin also can be directly toxic to fish and invertebrates at low concentrations. DDT residues in fish have been associated with reproductive problems such as early life-stage mortality.

Although not explicitly stated as such in the risk assessment, the assessment endpoints evaluated included the following:

- Protection of the benthic community from direct toxic effects
- Protection of other aquatic species from direct toxic effects
- Protection of birds from reproductive effects after food chain transfer
- Protection of fish from reproductive effects
- Ensuring that concentrations in edible species do not exceed thresholds for human health concerns.

The risk assessment utilized a thorough suite of measurements to evaluate the assessment endpoints (Table 5-3). Sediment sampling formed the foundation for the assessment. Sediment grab samples were collected from a total of 20 stations at the site. Samples for chemical analysis, benthic community evaluation, toxicity testing, interstitial water chemistry, and laboratory bioaccumulation testing all were taken from the same grab. Surface water, fish, crabs, shrimp, and benthic invertebrates from the site also were analyzed for chemical residues.

Table 5-3. Measurement endpoints and approach

Assessment endpoint	Measurement endpoints and approach
Protection of the benthic community from direct toxic effects	Benthic community structure compared to reference site; correlations with sediment and interstitial water chemistry
	Acute amphipod sediment toxicity test (survival); correlations with sediment and interstitial water chemistry; comparisons with reference site and historical information
	Chronic juvenile bivalve sediment toxicity test (growth); correlations with sediment and interstitial water chemistry
	Chronic bivalve laboratory sediment toxicity and bioaccumulation test
Protection of other aquatic species from direct toxic effects	Water concentrations compared with literature effects thresholds and AWQC[a]; modeling from sediment to water
Protection of birds from reproductive effects after food chain transfer	Prey concentrations; food web modeling from sediment through prey to receptors
Protection of fish from reproductive effects	Fish tissue concentrations at the site compared with literature effects thresholds; correlations with water, sediment, or prey concentrations; food web modeling from sediment through prey
Ensuring that concentrations in edible species do not exceed thresholds for human health concerns	Fish tissue concentrations at the site compared with FDA and cancer thresholds; correlations with water, sediment, or prey concentrations

[a]AWQC = ambient water quality criteria.

5.4.2.3. *Risk Characterization*

A detailed exposure evaluation was conducted using measurements from the site and equilibrium partitioning theory to support food web modeling and toxicity evaluations. Contaminants associated with three phases of the sediment matrix were examined (particles, freely dissolved, and associated with dissolved organic matter). Chronic and acute ambient water quality criteria values were exceeded in interstitial water at many of the stations. Organisms sampled near the site contained elevated concentrations of DDT metabolites and dieldrin in tissues; for sessile organisms, the concentrations correlated with sediment concentrations. DDT concentrations in shiner surfperch and bay goby were especially elevated and exceeded the Food and Drug Administration (FDA) action levels.

Benthic community evaluations indicated that increasing concentrations of DDT in sediment are associated with a reduction in the number of amphipods (especially after excluding one amphipod species that appeared to be more tolerant), and also was associated with an altered Infaunal Index. Ten-day sediment toxicity tests using *Eohaustorius estuarius* indicated that sediments near the site are significantly toxic to amphipods and that there is a gradient of toxicity away from the site. A toxic unit approach was used to evaluate the contribution of various contaminants present in the samples.

Food web modeling indicated that sediments appear to be a significant source of contaminants to birds and that the birds would be at risk, based on comparisons with literature effects thresholds. Fish-eating birds would need to feed exclusively near the site for 2 months each year to exceed risk standards. Risk was evaluated on a comparative basis between channels, with the channel nearest the site posing the greatest risk.

5.4.2.4. *Conclusions*

The risk assessment report concluded that the greatest risk was due to DDT compounds present in sediment nearest the site. The Lauritzen Channel was identified as a major contamination source, with tidal action transporting contaminated sediment and water away from the area. Organisms near the site are exposed to and accumulating high levels of DDT compounds.

A food web model was used to evaluate which areas of the site would need to be remediated to reduce risk to birds and fish to acceptable levels. The Lauritzen and Santa Fe Channels, plus some stations at the end of Richmond Inner Harbor, would require remediation on the basis of fish tissue concentrations found there. To reach protective concentrations in fish and benthic invertebrates, sediment concentrations would need to be between 200 and 500 g/g organic carbon (OC). Sediment concentrations exceeding 300 g total DDT/g OC were toxic to amphipods, and those exceeding 100 g/g OC had a reduced abundance of amphipods. This minimum effects threshold (100 g/g OC) represents a bulk sediment concentration of 1.9 mg/kg total DDT at 1.9% total organic carbon (TOC). The record of decision for the United Heckathorn site was signed on October 26, 1994, requiring the dredging of all soft bay mud from the Lauritzen Channel and Parr Canal, with monitoring to document that remediation goals for the site are achieved. The final remediation goals for the site include that the average sediment concentration be below 0.59 mg/kg total DDT, which should be protective of humans and fish-eating birds.

5.4.3. Metal Bank of America

5.4.3.1. *Site History and Background*

The Metal Bank of America site is located on the Delaware River in Philadelphia, PA. Between 1968 and 1973, transformer salvage operations were conducted at the site. The waste oil from the transformers was stored in an underground storage tank adjacent to the river. PCB oil from the tank and other operations at the site formed a light nonaqueous phase layer (LNAPL), which seeped into the mudflat and Delaware River adjacent to the site and resulted in an emergency removal action. As part of this action, an oil recovery system operated between 1983 and 1989. PCBs are the major contaminant at the site; however, polyaromatic hydrocarbons (PAHs), phthalate esters, and trace elements also have been detected in groundwater at the site. These contaminants may be present from the burning of electrical wire as part of metal recovery operations.

The Delaware River in the vicinity of the Metal Bank site provides habitat for Federal- and State-designated endangered shortnose sturgeon. Shad, herring, white perch, and catfish spawn near the site. Fishing advisories have been implemented in the river because of PCB contamination. Because the National Oceanic and Atmospheric Administration (NOAA) has technical expertise in aquatic ecological risk assessment and the site has the potential to adversely affect aquatic habitats and species for which NOAA serves as a natural resource trustee, NOAA was asked to conduct the aquatic ecological risk assessment for the site in support of EPA Region 3. The risk assessment report was finalized in March 1994.

5.4.3.2. *Problem Formulation and Conceptual Model*

Aquatic habitats of concern at the Metal Bank of America site include the surface waters, tideflats, and bottom substrates of the Delaware River, a freshwater tidal system. The shortnose sturgeon spend their entire life cycle in the Delaware River, and some of these fish may remain in the section of the river near the site following spawning. The river also provides habitat for a wide variety of other freshwater, estuarine, and anadromous fish species and benthic invertebrates such as blue crab.

PCBs were the primary contaminant evaluated for the risk assessment because of their elevated concentrations in groundwater, nonaqueous phase layer (NAPL), and sediment. PAHs, phthalates, DDT, and cadmium were secondary contaminants evaluated because of elevated concentrations in NAPL and/or sediment.

Exposure pathways were considered from surface water, NAPL, and sediment through ingestion (including food chain accumulation) and direct contact. Accumulation in biota was considered as the integrating pathway for PCB exposure. PCBs (and DDT) are known to elicit their most severe effects through bioaccumulation. The effect of PCBs of greatest concern to

NOAA is the potential for disruption of reproduction and toxicity to early life stages of fish after maternal transfer of PCBs to eggs. The other contaminants considered in the risk assessment (PAHs, phthalates, DDT, and metals) are known to have the potential for direct toxicity to sensitive benthic invertebrates and sensitive life stages of fish and other aquatic biota. Although not explicitly stated in the risk assessment report, the assessment endpoints considered by NOAA included:

- Protection of individual shortnose sturgeon from reproductive effects,
- Protection of populations of other fish from reproductive effects,
- Protection of benthic invertebrates from direct toxicity, and
- Protection of fish (including shortnose sturgeon) from direct toxicity.

Silvery minnows, channel catfish, and white perch were selected as representatives of the fish community near the site. Channel catfish are benthic species and would be exposed to contaminated sediments; they also were used as a surrogate species for shortnose sturgeon. Silvery minnows are forage fish that utilize mudflats near the site. White perch are abundant near the site and are recreationally important. Asiatic clams (*Corbicula fluminea*) were used to evaluate bioavailability of PCBs to benthic organisms and to evaluate the link from the site to fish through the food web.

5.4.3.3. *Measurement Endpoints and Approach*

For the assessment endpoints relating to the protection of fish from reproductive effects, tissue residue effect threshold concentrations were developed from the literature and compared with fish tissue concentrations of silvery minnow and channel catfish taken from near the site. For the endpoint relating to the protection of benthic invertebrates from direct toxicity, sediment concentrations were compared with toxicity threshold concentrations taken from the literature. Concentrations in NAPL, groundwater, and surface water also were evaluated for their potential toxicity to benthic invertebrates that may be exposed in the discharge area. The results of a qualitative benthic community assessment conducted in 1991 also were evaluated to determine whether the benthic community appeared to be at risk. For the assessment endpoint relating to direct toxicity to fish, concentrations in surface water were calculated for low-flow and average-flow conditions based on concentrations in groundwater and compared with ambient water quality criteria and maximum allowable toxicant concentrations from EPA guidance. Concentrations of contaminants in clams were used as evidence to link contamination at the site to concentrations in higher trophic levels and as an integrator of exposure throughout the mudflat area.

A weight-of-evidence approach was used for each assessment endpoint. The aquatic areas near the site were divided into three areas for evaluation based on the gradient of contamination. An area within 15 meters of the site contained the highest sediment PCB concentrations and was considered to be the discharge area for NAPL and groundwater. The mudflat within 30 meters of the site contained elevated concentrations of PCBs and other contaminants and was evaluated separately. Other areas of the mudflat and Delaware River near the site contained lower concentrations of the other contaminants and were considered as a third area for evaluation.

Tissue residue toxicity reference thresholds were developed from the literature by compiling available studies and selecting the 10th and 50th percentiles of the effect concentrations available. To evaluate sediment concentrations, both the arithmetic mean and 95% upper confidence interval were compared with effects range low, effects range medium, or apparent effects threshold concentrations (Table 5-4). Maximum allowable toxicant concentrations for the fathead minnow (for PCBs) were divided by 100 to account for lack of chronic toxicity information and to extrapolate for the lack of species-specific information for shortnose sturgeon and other fish species of concern.

5.4.3.4. *Risk Characterization*

Assessment endpoints relating to fish reproduction effects were evaluated using tissue residues and literature effects thresholds. Sampling of Asiatic clams and fish from near the site indicated that PCBs are accumulating in biota. PCB congener analysis of clams, sediment, and groundwater demonstrated a similar pattern of PCB accumulation as found in mudflat sediment and groundwater, indicating that the PCBs found in the clams come from the Metal Bank site. Asiatic clams from five stations in the mudflat contained 0.2 to 1.0 mg/kg total PCBs. Silvery minnows accumulated 0.55 to 2.8 mg/kg (whole body), and filets and whole-body channel catfish near the site contained 1.1 to 4.0 mg/kg (wet weight). Fish tissue (both silvery minnow

Table 5-4. Mean and upper 95% confidence limit (CL) concentrations (mg/kg) of total PCBs in sediments near the Metal Bank of America site normalized to dry weight and total organic carbon (TOC)

Area (N)	Dry weight mean	Upper 95% CL	TOC normalized mean	Upper 95% CL
Riprap (13)	5.9	9.4	150	240
Nearfield (<30)	3.8	5.0	79	110
Farfield (>30)	0.87	1.2	30	44

Effects range low: 0.023 mg/kg dry weight.
Effects range medium: 0.18 mg/kg dry weight.

and channel catfish) exceeded the 10th percentile tissue toxicity threshold (0.2 mg/kg) but not the median threshold (7.0 mg/kg), which indicates potential risk of reproductive problems in these species. Shortnose sturgeon may be at risk if they are more sensitive than channel catfish because of their longevity, habits, and higher lipid content. However, the relative sensitivity of shortnose sturgeon compared with catfish or other species is not known.

The potential for direct toxicity to benthic invertebrates was evaluated using sediment concentrations, literature toxicity thresholds, and benthic community analysis. Sediments in the mudflat contained up to 16 mg/kg total PCBs.

The benthic community survey conducted in 1991 did not include concurrent sediment analysis, so distance from the site was used as an indicator of PCB concentrations. Samples taken closer to the site exhibited reduced diversity. Sediment concentrations near the site greatly exceeded the highest toxicity thresholds for PCBs, PAHs, and phthalates, indicating that the benthic community is at risk. The risk is greatest in the area closest to the site. PAHs and phthalates do not exceed toxicity thresholds beyond 30 meters from the site, but risk from PCBs extends out into the Delaware River. Exposure to NAPL would result in acute toxicity due to high concentrations of PCBs, PAHs, and phthalates. It is most likely that benthic fauna would be affected if they were exposed to NAPL.

The potential for direct toxicity to fish was evaluated using calculated surface water concentrations and toxicity reference thresholds available from EPA guidance. Only PCBs exceeded toxicity thresholds in water. Predicted PCB concentrations for sturgeon (1.34-1.97 ng/L) exceeded toxicity reference concentrations (1 ng/L) only within 15 meters of the site. The water threshold was exceeded in this area by only a factor of 2.

Discharges of NAPL would be expected to be confined to a small area near the riprap. However, concentrations of PAHs, phthalates, and PCBs in NAPL exceeded toxicity reference concentrations by five orders of magnitude, and acute effects to any fish directly exposed to NAPL would be expected.

5.4.3.5. *Conclusion*

The risk assessment concluded that the Metal Bank of America site posed risk to fish reproduction (including shortnose sturgeon) and to the benthic community in the mudflat adjacent to the site. A major strength of the risk assessment was the inclusion of a substantial analysis of uncertainty around the data and conclusions. The risk assessment identified that the major concern for the site is the effects of bioaccumulation of PCBs in fish and shellfish, which demonstrates integrated exposure through surface water, sediment, and food web pathways. This information is providing the basis for the selection of a remedy to reduce sediment contamination to concentrations below those associated with reproductive effects in fish and to control the discharge of contaminated ground water and LNAPL. The data also will provide the basis for monitoring effectiveness of a remedy for the site. A final record of decision is expected in 1997.

Although no threshold concentrations for sediment were provided in the risk assessment for sediment for reproductive effects, relationships between sediment and biota concentrations calculated in the risk assessment were used to estimate protective sediment concentrations based on site-specific bioavailability and effects thresholds from the literature. The risk assessment provides an evaluation and compilation of available tissue residue effects concentrations for PCBs that has proven useful at other PCB sites throughout the country.

5.4.4. Data Quality Objectives Process

This section is an example of a process, not of a specific case study. Federal agencies manage a wide variety of ecological resources at various sites. Diverse sites, such as many of those found throughout DOE and the U.S. Department of Defense (DoD), pose many technical challenges that are not typically associated with smaller, simpler sites (e.g., industrial and commercial sites measured in acres, sites with single contaminants, sites without radionuclide contaminants). For example, DOE and DoD sites may include relatively undisturbed and sensitive habitats (e.g., wetlands, semiarid deserts), threatened and endangered species, woodland habitats, former agricultural lands, and highly disturbed industrialized lands. On any given site, specific types of ecological resources may occur entirely within the site boundaries or may be distributed across and beyond site boundaries.

These sites have a great range of contaminant profiles, sizes, climates, elevations, biomes, ecosystems, and habitat types. The assessments are complex and vary greatly in purpose, scope, approach, and implementation. Therefore, the ability to increase the efficiency and effectiveness of ecological risk assessments by a more standardized design and conduct is important. The data quality objectives (DQO) process developed by EPA (1994) offers an effective means of achieving this objective, and it is being used to assist in the design and conduct of some ecological risk assessments by DOE and other Federal agencies. The DQO process also offers risk assessors and other participants a means for identifying and substantiating necessary changes in scope, approach, cost, and schedule change for technical reasons during the conduct of the assessment.

Role of the DQO Process in Ecological Risk Assessment

The DQO process involves the following seven steps:

1. State the problem
2. Identify the decision
3. Identify inputs to the decision
4. Define the study boundaries
5. Develop a decision rule
6. Specify tolerable limits on decision errors
7. Optimize the design for obtaining data.

The DQO process offers risk assessors a standardized procedure for designing an effective, efficient risk assessment. It is a strategic planning-based approach whose objective is to ensure that "data of sufficient quality and quantity to support defensible decision making" are collected, without "unnecessary, duplicative, or overly precise data" being collected (U.S. EPA, 1993). The DQO process meets this objective through the application of seven planning steps (based on the scientific method) that are "designed to ensure that the type, quantity, and quality of environmental data used in decision making are appropriate for the intended application" (U.S. EPA, 1993).

5.5. NATURAL RESOURCE DAMAGE ASSESSMENT AND ECOLOGICAL RISK ASSESSMENT

5.5.1. What Is Damage Assessment?

CERCLA Section 107(a)(4) (c) establishes liability for damages for injury to, destruction of, or loss of natural resources, including the reasonable costs of assessing such injury, destruction, or loss. Natural resources are defined to include land, fish, wildlife, biota, air, water, groundwater, and drinking water supplies and other resources belonging to, managed by, held in trust by, appertaining to, or otherwise controlled by the United States, any State or local government, any foreign government, or any Indian tribe. Natural resource damage assessment is the process used to assess damages to natural resources from releases of oil or hazardous substances and to obtain compensation to restore injured natural resources and their services. The damage assessment process used by natural resource trustee agencies is guided by a series of regulations. Under the National Contingency Plan, natural resource trustees are defined to include States, tribes, and five Federal agencies (the Departments of Commerce, Interior, Agriculture, Energy, and Defense).

Regulations describing procedures for assessing damages to natural resources from discharges of oil or releases of hazardous substances under CERCLA were promulgated by the U.S. Department of the Interior (DOI) and can be found in 43 CFR Part 11. Recently, NOAA promulgated regulations describing procedures applicable to oil spills under the Oil Pollution Act of 1990 (OPA), which can be found in 15 CFR Part 990. The paradigm for conducting damage assessments embodied in the OPA regulations also is being adopted for CERCLA damage assessments.

Under the OPA regulations, the assessment process involves three phases: preassessment, restoration planning (including injury assessment and selection of appropriate restoration measures), and restoration implementation. Preassessment activities include determining if natural resources are in the affected area and if they have been exposed to the contaminants, as well as whether the resources could have been injured by the release. Preliminary evidence for injury is compiled in this stage, and at the conclusion of the preassessment, natural resource trustees should be able to decide whether to proceed with restoration planning activities. Restoration planning is directed toward evaluating potential injuries to determine the need for and scale of restoration activities. Injury assessment activities determine the nature and extent of injuries to natural resources and the services they provide. Following this assessment, restoration options are evaluated to determine their potential for returning natural resources to their condition had the injury from the release not occurred. Restoration implementation entails carrying out projects that compensate the public for the injured natural resources and services. Responsible parties are liable for the cost of restoration and for reasonable assessment costs.

5.5.2. Contrasts Between Ecological Risk Assessment and Damage Assessment

The CERCLA lead response agency is responsible for conducting an ecological risk assessment. Natural resource trustees are responsible for conducting damage assessments. In accordance with Section 107(f)(1), natural resource damages must be used to restore, replace, or acquire the equivalent of injured natural resources. An ecological risk assessment can provide information on injuries to natural resources, but by law Superfund money may not be used to conduct damage assessments. Injury is defined by regulation as death, disease, behavioral abnormalities, cancer, genetic mutations, physiological abnormalities, and physical deformities.

The objective of ecological risk assessment is to determine whether an ecological risk is present at a site, link the risk to site-specific contamination, and provide sufficient information to determine site action. The link between exposure to contaminants and adverse effects is critical in an ecological risk assessment. To justify a remedial action based on ecological concerns, a risk assessment must establish that an actual or potential ecological threat exists at the site. The natural resource damage assessment process requires the trustees to demonstrate that injury has occurred to natural resources and services, not just that there is potential ecological risk. This typically requires that extra quality assurance information is collected or more rigorous studies are conducted, especially in the event that the damage assessment must withstand court challenge.

An ecological risk assessment can provide necessary information for a damage assessment because it establishes a causal link between site contaminants and adverse effects and provides information concerning injury, but it may not provide a complete assessment of all injuries to natural resources. Ecological risk assessments are designed to evaluate baseline ecological risk and often evaluate the most sensitive receptors present, to ensure that all biota at the site are protected. In contrast, natural resource damage assessments may focus on particular representative species of interest to the trustees (for example, recreationally important species) that may or may not be the most sensitive receptors present.

5.5.3. Requirement for Coordination of Assessments

CERCLA and the NCP require the lead response agency to coordinate assessments with the natural resource trustees and to notify the trustees when potential injury is identified. This requirement benefits all participants in the remedial process because early involvement of the trustees can improve ecological risk assessment and can facilitate the settlement of liability at the end of the process.

5.6. RISK ASSESSMENT METHODOLOGY DEVELOPMENT

Methodology development areas of particular interest under CERCLA include the following:

- Address design needs specific to ecological risk assessments in the work plan phase, including interested parties and management needs.
- Improve exposure/effects models, extrapolation techniques for various exposure pathways, and validation techniques.
- Develop the use of chemical bioavailability, additional tissue-based toxicity thresholds, and scientifically sound thresholds for screening values for soil contaminants.

5.7. SITE REMEDIATION AND THE ROLE OF ECOLOGICAL RISK ASSESSMENT

Superfund risk managers typically address three key questions at every site: (1) Do site releases present an unacceptable risk to important ecological resources? (2) If the answer is yes, should the site be actively cleaned up or will the remedy do more damage (and thus not provide short-term protectiveness)? and (3) If cleanup is warranted, how do you select a cost-effective response and cleanup levels that provide adequate protection?

As was seen in the case studies, EPA considers the results from a battery of toxicity tests, field studies, and food-chain models to determine whether or not observed or predicted adverse effects are unacceptable. It can then use the same studies to select chemical-specific cleanup levels that are believed to be protective at that site.

Whether or not to clean up a site is often the most difficult risk-based decision to make. Even though an ecological risk assessment may demonstrate that unacceptable ecological effects have occurred or are expected to occur in the near future, removal or in situ treatment of the contamination may do more ecological damage (often due to widespread physical destruction of habitat) than leaving it in place. When evaluating remedial alternatives, the NCP highlights the importance of considering the long-term and short-term impacts of the various alternatives in determining which alternatives "adequately protect human health and the environment." A remedy that does significant short-term ecological damage often would not be considered to meet the NCP threshold criteria of "protective."

Assuming remediation is technically practicable and not cost prohibitive, risk managers consider the long- and short-term ecological impacts of active remediation versus natural attenuation of the contaminants. The evaluation of ecological impacts from implementing remedial alternatives is part of the ecological risk assessment process and should be discussed in a feasibility study. In most cases, unless they are very large, sites with persistent contaminants that are also mobile are remediated. At sites with contaminants that degrade or with sediment contaminants that will become unavailable because of natural deposition of uncontaminated sediment over them, preventing additional releases may be the most appropriate remedy.

Before making a response decision, the risk manager, in consultation with an ecological risk assessor, often considers many of the following factors:

- The magnitude of the observed or expected impacts of site releases on the affected ecosystem component (e.g., fish population, benthic community)
- The likelihood that these impacts will occur or continue
- The size and functional value of the impacted area in relation to the larger ecosystem

- Whether or not the impacted area is a highly sensitive or ecologically unique environment

- The recovery potential of the impacted ecosystem and expected persistence of the chemicals of concern under the site conditions

- Short-term and long-term impacts of the remedial alternatives on the site habitat and larger ecosystem

- Effectiveness of the remedy; that is, whether there are other continuing, nearby, non-Superfund releases or other types of stressors that will continue to adversely impact the ecosystem after the cleanup is implemented

- Community opinion on the value of the affected portion of the ecosystem and of the natural resources affected

- Whether or not there will be any remaining residual risks that may need to be addressed by a natural resource trustee.

It is the responsibility of the risk manager, in consultation with the risk assessor, to select a remedy and ensure cleanup levels for the site that are reasonable. This decision can be made only after a thorough consideration of all nine criteria described in the NCP. Because of the high complexity of ecosystems and the large number of species potentially affected at every site, there will usually be a relatively high degree of uncertainty concerning the levels deemed to be protective—are they too high or too low? At these sites, monitoring of the affected ecological receptors should be performed after the remedy has been implemented in order to determine if recovery is occurring in a reasonable time frame and whether or not an additional response action is warranted.

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POTENTIAL USES OF
ECOLOGICAL RISK ASSESSMENT

6. AGRICULTURAL ECOSYSTEMS

6.1. SUMMARY

The U.S. Department of Agriculture (USDA) has primary responsibility for agricultural production issues. Mandatory risk assessment of production agriculture has been established only recently. The Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994 established new statutes for regulatory analysis requirements of Department regulations. Included is the requirement of a risk assessment and cost-benefit analysis for all proposed major regulations, defined as regulations having an annual economic impact of $100 million and primarily affecting human health, human safety, or the environment. Two of the case studies in this chapter are USDA conservation programs that were conducted under the risk assessment requirement, while the other case study involves shrimp aquaculture.

The aquaculture case study followed EPA's ecological risk assessment approach but had proceeded only as far as problem formulation at the time this report was prepared. The assessments done for the USDA conservation programs relied heavily on the ecological risk assessment approach in the early stages of development, but the assessment teams modified some aspects of the framework to address: specific agency requirements, scope and scale issues, and management goals for the associated regulations. As a result, there was some deviation from the ecological risk assessment process. For example, the time and information available for the assessment necessarily limited the degree of detail and quantization possible in the assessment. Due to statutory mandates and other factors, identified assessment endpoints did not always involve an ecological entity and attribute. And, as with the nonindigenous species chapter, there was some overlap of risk assessor and risk manager roles; in risk characterization, there was strong emphasis on providing results directed at risk management objectives.

The two USDA conservation program assessments included in this chapter were done for the new Environmental Quality Incentives Program (EQIP) and the revamped Conservation Reserve Program (CRP). Both programs seek to reduce the adverse impacts of agricultural practices on natural resources on and off the farm. EQIP provides assistance to producers to encourage the application of conservation strategies to farming activities that can result in environmental degradation. CRP enrolls the most environmentally sensitive cropland into permanent resource-conserving covers for 10-15 years. The objectives of the EQIP and CRP assessments included (1) identifying those agricultural activities and practices that place natural resource values at risk; (2) characterizing the mechanisms that result in risk; (3) characterizing the magnitude and extent of the environmental risk; and (4) where possible, making recommendations to risk managers and decision makers on how the results of the assessment can be used in program development and implementation.

In problem formulation, both assessments developed assessment endpoints, conceptual model diagrams, and analysis plans. Both assessments were largely qualitative in focus. EQIP focused on agricultural practices posing risks to the environment, including crop production and grazing and livestock production. Conceptual diagrams were developed to hypothesize the cause-and-effect pathways of environmental risk. These pathways were associated with (1) soil/land disturbances, (2) irrigation water application, (3) pesticide application, (4) nutrient application, (5) brush and noxious weed invasion, (6) pasture grazing, (7) rangeland disturbance, and (8) confined livestock production. A qualitative evaluation of ecological effects was based on analysis of these pathways and interpretation of agricultural use and impact maps for the continental United States. The assessment presented the principal causes of use and quality impairment of rivers, streams, lakes, estuaries, reservoirs, and ponds from agricultural activities by region in tabular form. Data were presented as miles of use impairment and percentage of water quality impairment from such factors as pesticides, sediment, pathogens, and salinity. Livestock concentrations on a per-State basis also were presented to indicate where environmental stressors from associated activities might be the greatest. The risk characterization section of the assessment identified the magnitude of environmental consequences and delineated how those consequences can be addressed by proven on-farm conservation strategies. It discussed the potential for risk reduction and EQIP baseline comparisons and summary conclusions based on the four previous conservation programs replaced by EQIP. The risk characterization focused mainly on recommendations to risk managers. The assessment team attempted to analyze where the cumulative effects or impacts of agricultural activities are occurring across the United States. Both recovery of ecological systems and major uncertainties in the assessment were discussed.

For CRP, the task was complicated by the huge scope and complexity of the problem; as many as 36.4 million acres of environmentally sensitive cropland have been enrolled in the program. It was extremely difficult to establish detailed and consistent databases that empirically describe the stressor-environmental component relationships and their impacts. Problem formulation was similar to that for EQIP, but, in contrast, the CRP conceptual diagrams were limited to crop production activities and did not include livestock and grazing components. Analysis of ecological effects were similar for EQIP and CRP. The main difference is that the CRP analysis was based, in places, on evaluating the potential impacts as if there had not been a CRP in place for more than 10 years. For risk characterization, the assessment team addressed the identity and location of the type of cropped acreage that should receive priority for enrollment in CRP. The risk assessment will help national-level policy makers to generally target the situations and areas where participation in the program is most likely to address environmental degradation. With this information, national-level policy makers can work with the States and localities in these areas to refine the application of CRP activities toward solutions to the environmental problems. As with EQIP, major uncertainties and time to natural resource recovery were discussed. However, in contrast with EQIP, no direct recommendations to risk managers were made in this assessment.

The third case study addresses the potential introduction and spread of nonindigenous pathogenic shrimp viruses to shrimp aquaculture and to the wild shrimp fishery in the United States. Outbreaks of these viruses on U.S. shrimp farms and the appearance of diseased shrimp in U.S. commerce prompted the Federal interagency Joint Subcommittee on Aquaculture to initiate an ecological risk assessment. Following EPA's ecological risk assessment guidelines process, a problem formulation step was used to develop a conceptual model, list the potential effects of the viruses on shrimp and other aquatic species, summarize the basic life history of shrimp, identify potential stressors affecting the shrimp population, and identify potential pathways for the exposure of wild shrimp to the viruses. After using the framework as a tool for organizing information, the work group proposed several options for doing an assessment. It also recommended that a formal ecological risk assessment be done to provide information needed to address international trade issues, national and State regulatory obligations, and the needs of industry, environmental groups, and the public.

The challenge to government agencies that conduct risk assessment on agricultural production is to develop an iterative process early in regulatory development. This includes identifying when risk assessment will be required, clearly identifying risk management objectives, and establishing an iterative process between risk assessment and risk management for the course of program development. Also, it is necessary that there be clearly identified strategies for using these tools so that programs can minimize adverse ecological impacts while achieving other agricultural goals. Risk management must play a role in the development and use of risk assessments if the intent is for risk assessment to aid in the decision-making process of regulatory development.

6.2. INTRODUCTION

Federal agencies traditionally have used a variety of tools to influence the impact of agriculture on ecological resources. These tools include regulations, research and development, training and education, financial incentives, and information management. In some cases, ecological risk assessments are now being used to aid decision makers in using these traditional tools more effectively.

6.2.1. Historical and Current Use of Risk Assessment in Agricultural Production

6.2.1.1. *Environmental Impacts of Production Practices*

Agriculture is a multifaceted industry that depends heavily on the availability of sustainable land, water, plant, and animal resources. However, agricultural production generally has had an adverse impact on these resources and on the ecological framework (both on and off the farm) that ties the resources together in a sustainable way. Future demand for food and fiber requires a balancing of agricultural production technologies and ecological principles to create agroecosystems capable of high levels of production on a sustainable basis with minimum adverse off-site impacts.

Although some persons question the validity of applying the term "ecosystem" to farmed land, there is no question that there are ecological interactions and relationships on farmed land. These encompass climatic changes, soil quality factors, water quality and quantity, desirable and undesirable insects, diseases, small mammals, bird species, and other forms of wildlife that have adapted to agricultural landscapes. Although these interactions are not part of a "natural" ecosystem, they still exist and offer opportunities to apply ecological principles about energy flow, nutrient cycling, and biodiversity that can help promote sustained productivity.

Ecological risk assessment has played only a minor role in agricultural development in the United States. This limited use is largely the result of timing. Most of the modern agricultural system was in place before risk assessment came into use. However, agriculture continues to evolve, and risk assessment is now being done to support public decision making about land-use policies, new technology, and alternative production systems.

By 1920, most of the lands in the United States that could be used for agriculture were already in production. About 500 million acres were used for growing crops, including hay production. Another 700 to 800 million acres of public and private lands were used for livestock grazing.

By the 1950s, most of the technologies associated with modern agriculture were already widely used and today are continually refined. These technologies include the introduction of exotic plants and animals, plants produced in monoculture, chemical fertilizers and pesticides, irrigation, mechanization based on the internal combustion engine, and barbed-wire fencing. Applying these technologies to the vast land areas used for agricultural production has had a significant impact on ecological systems, both on and off the farm.

The U.S. Department of Agriculture (USDA) has primary responsibility for agricultural production issues. The U.S. Department of the Interior, through the Bureau of Land Management, manages the majority of public lands leased for grazing livestock, in concert with the Forest Service. (Any risk assessments conducted with regard to these lands are discussed in Chapter 8.) This leaves USDA to address the issues associated with production on private lands.

Agencies within USDA regularly conduct risk assessments for various activities of the Department. Some of these activities are discussed elsewhere in this report. However, mandatory risk assessment of production agriculture has been established only recently. The Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994 established new statutes for regulatory analysis requirements of Department regulations. Included is the requirement of a risk assessment and cost-benefit analysis for all proposed major regulations (Public Law 103 [PL 103]). For purposes of this statute, a major regulation is defined as one that has an annual economic impact of $100 million and primarily affects human health, human safety, or the environment. The Reorganization Act requires USDA to conduct thorough analyses that make clear the nature of the risk being managed, the reasoning that justifies the proposed rule, and a comparison of the likely costs and benefits of reducing the risk. The Reorganization Act also established the Office of Risk Assessment and Cost-Benefit Analysis, whose function it is to ensure that these analyses are based on reasonably obtainable and sound scientific, technical, economic, and other data.

6.2.1.2. *Environmental Impacts on Production*

Although ecological risk assessments on the impacts of biological, physical, and chemical stressors on agricultural production are not common, some work has been done and more is planned for the future. One example is a risk assessment conducted on wildlife damage to field corn (Wywialowski, 1996). In another example, EPA's report Framework for Ecological Risk Assessment (U.S. EPA, 1992) was used by the National Crop Loss Assessment Network (NCLAN) to develop an approach for assessing the impact of ozone on crop production (U.S. EPA, 1993). A goal of the NCLAN risk assessment was to provide risk managers with a better understanding of the potential impacts of ozone on crop production and develop more appropriate ozone standards. The regulatory impetus behind this study was the Clean Air Act (1970), which required EPA to set National Ambient Air Quality Standards (NAAQS) for "any air pollutant which, if present in the air, may reasonably be anticipated to endanger public health or welfare." EPA is responsible for developing and promulgating both primary (human health) and secondary (public welfare) NAAQS. The 1977 amendments to the Clean Air Act required that the criteria for the NAAQS be periodically reviewed and revised to include new information. In 1978, EPA conducted a review of the literature to determine the impact of ozone on vegetation and published an analysis. As a result of the analysis, EPA accepted the primary ozone standard as a reasonable secondary standard. However, the credibility of this "secondary" standard suffered, and NCLAN was established to conduct a study to assess the impact of ozone on agricultural resources and to provide the most useful data and criteria for the review of the standard. At the time of this writing, the study has played a significant role in the proposed new secondary standard for ozone.

The NCLAN study was initiated by EPA as a risk assessment and, with some modification, followed the four steps of EPA's framework report: problem formulation, characterization of ecological effects, characterization of exposure, and risk characterization. In problem formulation, the relevant ecological components were identified and described, and relevant endpoints defined. Next, ozone exposure-plant response was studied experimentally in the field, and ecological effects response models were developed. The exposure characteristics then were described and documented. Finally, risks were characterized in both crop yield and economic terms.

As a national risk assessment, NCLAN was limited by time and funding constraints. As a result, there was limited spatial representativeness (there were only six sites for a national assessment) and few experimental designs implemented to assess the effects of interacting stressors (U.S. EPA, 1993). Nonetheless, the results of the ecological risk assessment did play a significant role in developing the proposed new secondary standards for ozone.

6.2.1.3. *Environmental Impacts of Aquaculture*

Aquaculture systems have expanded rapidly in recent years. Although these production systems have the potential to impact significantly on aquatic ecosystems, public policies for these new systems were made without the benefit of an ecological risk assessment until recently. Regulatory control over aquaculture production is shared by several agencies, including the National Oceanographic and Atmospheric Administration, National Marine Fisheries Service, U.S. Fish and Wildlife Service, Animal and Plant Health Inspection Service (USDA), and EPA. State agencies are also heavily involved in establishing permit (effluent) and production regulations.

Ecological risks associated with aquaculture are now coming into focus. Aquaculture systems, such as catfish production in the southern States, are the aquatic equivalent of feedlots for cattle, hogs, and poultry. However, with aquaculture, pollutants and pathogens, via effluents, have a greater potential to impact natural aquatic ecosystems because of the similar or identical trophic levels of potential receptor species. Periodic draining of catfish ponds contributes to (1) increased turbidity, (2) organic, pesticide, and nutrient loading, and (3) in some situations, adding chemicals used for disease treatment into receiving water bodies. There is also a potential risk that wastewater could transport pathogens to wild species.

Another potential ecological impact of aquaculture is the threat to native species from farm stock escapees. For example, the wild Atlantic salmon is facing genetic alteration from escapees from Norwegian fish farms. These farms expect to produce 330,000 tons of Atlantic salmon this year, compared with a total wild Atlantic salmon catch of 3,800 tons in 1995. The fish in these farms have been selected over five generations for fast growth and a high fat content.

In 1995, between 200,000 and 650,000 domesticated salmon escaped and intermingled with native fish. In addition to crossbreeding, the fish raised in confinement are known to carry parasites such as sea lice, and although vaccinated, they also may carry pathogenic bacteria and viruses to native fish species.

Based on these and similar experiences, ecological risk assessment is now being done on selected aquaculture production systems.

6.2.2. Applicability of EPA Ecological Risk Assessment Framework and Guidelines to Agricultural Ecosystems

Only recently has ecological risk assessment been used in public policy decision making for agricultural issues. With hindsight, we can see benefits that could have been derived by applying our existing understanding of ecological risk assessment to agricultural development over the past 200 years. Such assessments could have aided in mitigating adverse ecological impacts in many ways. For example, public programs for conserving soil and water resources, regulating agrochemicals, protecting ecologically sensitive areas, and controlling the introduction of exotic species could have been put in place before millions of acres of land were put into production and new technologies promoted.

Such assessments also could have played a role in using agriculture more effectively in protecting ecological values. Many wildlife and fish species benefit from such agricultural activities as planting of shelterbelts, building of ponds and other water retention facilities, planting crops that provide winter feed, and controlling fire and disease. Earlier ecological assessments might have resulted in a more systematic development of such benefits.

Human ecology also has been profoundly affected by agriculture. American society would not be the same without the benefits derived from its solid agricultural foundation. Earlier ecological risk assessments could have led to policies that would have made these benefits even greater. For example, understanding the impacts of overgrazing and plowing fragile lands could have mitigated the worst excesses of the Dust Bowl. Early ecological risk assessments also might have identified the value of farmlands in regulating urban growth and might have resulted in farmland protection policies that would have prevented some urban congestion.

Despite its long history, agriculture continues to be a dynamic process, with the continual development of new technologies, conservation measures, and production systems. The three case studies provided in Section 6.3, two on the USDA conservation programs and one on aquaculture, all relied heavily on the EPA framework report and on the report Draft Proposed Guidelines for Ecological Risk Assessment (U.S. EPA, 1996). In the early stages of development of the risk assessments, the guidelines report was not yet completed. Working outlines for the assessments were developed using the framework report, but modifications were necessary because of the scope and scale of the assessments and the physical and chemical nature of the multiple stressors being assessed. In addition, there was strong emphasis in the risk characterization process on providing results directed at risk management objectives.

6.3. CASE STUDIES

The two case studies presented in Section 6.3.1 concern nationwide, multiple-stressor risk assessments conducted by two agencies in USDA. These assessments were the first conducted under the risk assessment requirement of the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994. The third case study (Section 6.3.2) is an interdepartmental report developed to provide the Joint Subcommittee on Aquaculture with a basis for discussing and selecting among a range of options for conducting a risk assessment on shrimp viruses. This report was developed using EPA's framework and guidelines reports (U.S. EPA, 1992, 1996) and followed these documents very closely. The assessments done for the USDA programs relied heavily on the framework report in the early stages of development. However, the assessment teams found these documents, in places, to be either unduly restrictive or inadequate for the scope, scale, and purpose of the assessments given the management goals for the associated regulations. The result is that there is some deviation from the framework and guidelines reports in these assessments, particularly with regard to the development of assessment endpoints and the focus of the risk characterization sections of the documents. The framework report will probably continue to be modified, as needed, for use in USDA program and regulation development.

6.3.1. Risk Assessment of USDA Conservation Programs

As far as can be determined, only two ecological risk assessments of agricultural production impacts using the EPA framework and guidelines reports have been conducted by a Federal agency—namely, USDA—as the result of new congressional mandate P.L. 103. These two assessments were done for the new Environmental Quality Incentives Program (EQIP) and the revamped Conservation Reserve Program (CRP). Both programs seek to reduce the adverse impacts of agricultural practices on natural resources on and off the farm. These resources include soil and water, wetlands, and wildlife habitats. EQIP provides for cost-sharing funds, incentive payments, and technical and educational assistance to producers to encourage the application of conservation strategies to farming activities that can result in environmental degradation. CRP enrolls the most environmentally sensitive cropland into permanent resource-conserving covers for 10-15 years.

Ecological risk assessments were done on both of these programs (FSA, 1997; NRCS, 1997). The objectives of the assessments included (1) identifying those agricultural activities and practices that place natural resource values at risk; (2) characterizing the mechanisms that result in risk; (3) characterizing the magnitude and extent of the environmental risk; and (4) where possible, making recommendations to risk managers and decision makers on how the results of the assessment can be used in program development and implementation.

In assessments for both programs, the resources to be considered at risk—soil and water, air, wetlands, wildlife habitat, and grazing lands—were provided by draft regulation before conducting the assessments. This led to the development of assessment endpoints that might not be considered common under the EPA framework and guidelines reports. The risk assessors for the two programs determined that endpoints such as air quality and cultural and historic resources are intimately and ecologically associated with the designated resources. They are at risk from the impacts of some agricultural practices and should be considered in the management decisions made in the two programs.

6.3.1.1. *Environmental Quality Incentives Program*

6.3.1.1.1. *Background*. EQIP has four environmental mandates: (1) combine into a single program the functions of the rescinded Agricultural Conservation Program, the Great Plains Conservation Program, the Water Quality Incentives Program, and the Colorado River Basin Salinity Control Program; (2) execute EQIP in a manner that maximizes environmental benefits per dollar expended; (3) provide flexible technical and financial assistance to farmers and ranchers who face the most serious threats to soil, water, and related natural resources, including those threats to grazing lands, wetlands, and wildlife habitats; and (4) provide assistance to farmers and ranchers to comply with the Conservation Title of the 1996 Farm Bill and other Federal and State environmental laws.

In creating EQIP, Congress, in the Federal Agriculture Improvement and Reform Act of 1996, provided an initial identification of environmental resources considered at risk. These resources were identified as soil, water, and related natural resources, including wetlands, grazing lands, and wildlife habitats. However, in conducting this assessment, several additional resources were identified at risk: (1) air quality, (2) cultural and historic resources, and (3) landscape resources.

The assessment consisted of technical evaluations and analyses that attempted to characterize the relationships among agricultural production activities, ecosystem stressors, and resulting adverse ecological effects on particular natural resources. The assessment had three sections: (1) problem formulation, (2) analysis of ecological effects, and (3) risk characterization.

6.3.1.1.2. *Problem formulation*. Problem formulation includes an analysis plan, a brief discussion on identification of missing data, and recommendations for additional data collection, analysis, and evaluation. During the problem formulation stage, data were gathered and used to identify those agricultural practices or activities posing the greatest risks to the environment. These were identified generally as crop production and grazing and livestock production. Conceptual diagrams were developed to hypothesize the cause-and-effect pathways of environmental risk. These pathways were associated with (1) soil/land disturbances, (2) irrigation water application, (3) pesticide application, (4) nutrient application, (5) brush and noxious weed invasion, (6) pasture grazing, (7) rangeland disturbance, and (8) confined livestock production. Examples of two of the conceptual diagrams are presented in Figures 6-1 and 6-2.

Identified in the conceptual diagrams were the specific assessment endpoints associated with the resources at risk: structure of off-site resources and habitats, livestock or plant yields, wetland functions, viability of aquatic communities, good air quality, survival of threatened or endangered species, extent of natural habitats, quality of cultural resources, potable water supplies, diversity of terrestrial and avian wildlife species, survival and diversity of terrestrial and avian communities, function of riparian areas, diversity of natural habitats, and quality of landscape resources. Aquatic communities, threatened and endangered species, wetlands, livestock and plant yields, potable water supplies, air quality, and terrestrial and avian wildlife communities were assessment endpoints common to most hypothesized pathways. This reflects the interconnectivity of agriculturally related natural resources. A detailed discussion of the risk initiators, system stressors, ecological effects, and assessment endpoints identified in the diagrams was included in the assessment.

6.3.1.1.3. ***Analysis of ecological effects.*** Owing to the lack of comprehensive data and the uncertainties associated with extrapolation of site-specific data to a landscape scale, the analysis

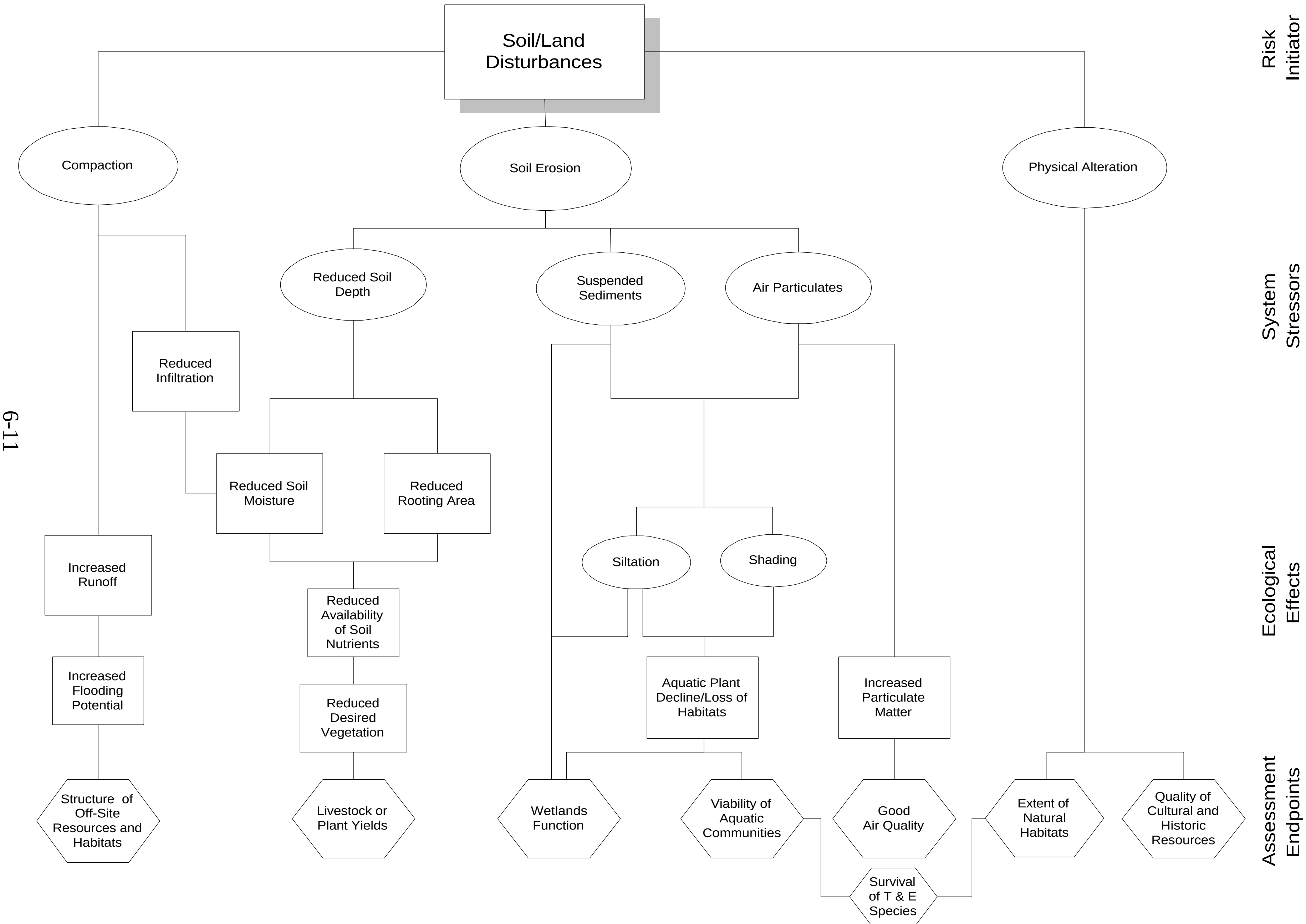

Figure 6-1. Conceptual diagram of soil/land disturbances.

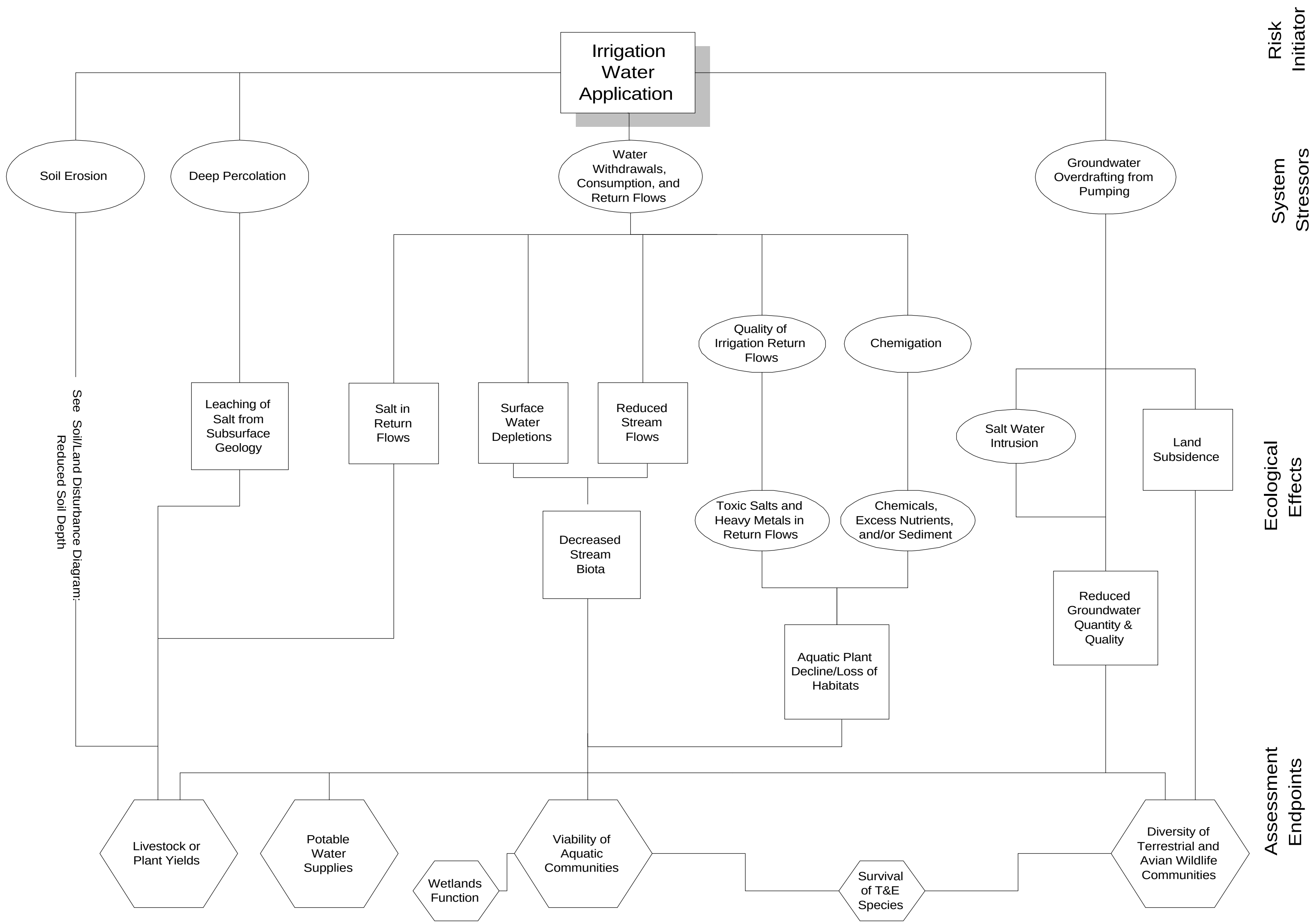

Figure 6-2. Conceptual diagram of irrigation water application.

of the hypotheses developed through the conceptual diagrams is in qualitative, narrative form. The discussion centers on the previously identified resources at risk and provides an overall evaluation of the types and kinds of activities found to be placing the natural resources at risk.

With available data, and in cooperation with the Natural Resources Inventory (NRI) staff, maps of the continental United States were generated indicating the status (based on 1992 data) of agriculturally related land uses and potential or actual impacts of agricultural activities. These included maps of acres in cropland, wind and water erosion on cropland, sediment delivered to rivers and streams from sheet and rill erosion on farm fields, cropland with conservation needs, potential nitrogen and phosphate fertilizer loss from farm fields, pesticide runoff and leaching potential by watershed for field crop production, irrigated cropland, rangeland status, palustrine wetlands on croplands, and others. Examples of the maps are given in Figures 6-3 and 6-4.

The assessment presented the principal causes of use and quality impairment of rivers, streams, lakes, estuaries, reservoirs, and ponds from agricultural activities by region in tabular form. Data were presented as miles of use impairment and percentage of water quality impairment from such factors as pesticides, sediment, pathogens, and salinity. Livestock concentrations on a per-State basis also were presented to indicate where environmental stressors from associated activities might be the greatest.

6.3.1.1.4. ***Risk characterization.*** The risk characterization section of the assessment identified the magnitude of environmental consequences and delineated how those consequences can be addressed by proven on-farm conservation strategies. It discussed the potential for risk reduction and EQIP baseline comparisons and summary conclusions based on the four previous conservation programs replaced by EQIP. The risk characterization focused mainly on recommendations to risk managers. The assessment team attempted to analyze where the cumulative effects or impacts of agricultural activities are occurring across the United States. By using thematic maps of the different resource or landscape features, resources and areas can be rated as to their risk of degradation. In this manner, a more accurate picture of the types, locations, and extent of agricultural activities and their relationship to environmental resources potentially at risk can be ascertained.

Cumulative effects also were assessed, to the extent possible, in an effort to provide risk managers with a more complete, in-depth analysis for use on an ecoregion basis. The 10 agricultural production regions of the country were used to represent ecoregions. This choice was made because the States included within each agricultural production region were found to have environmental or ecological similarities. Also, many of the available environmental data used in this assessment were already presented in this format.

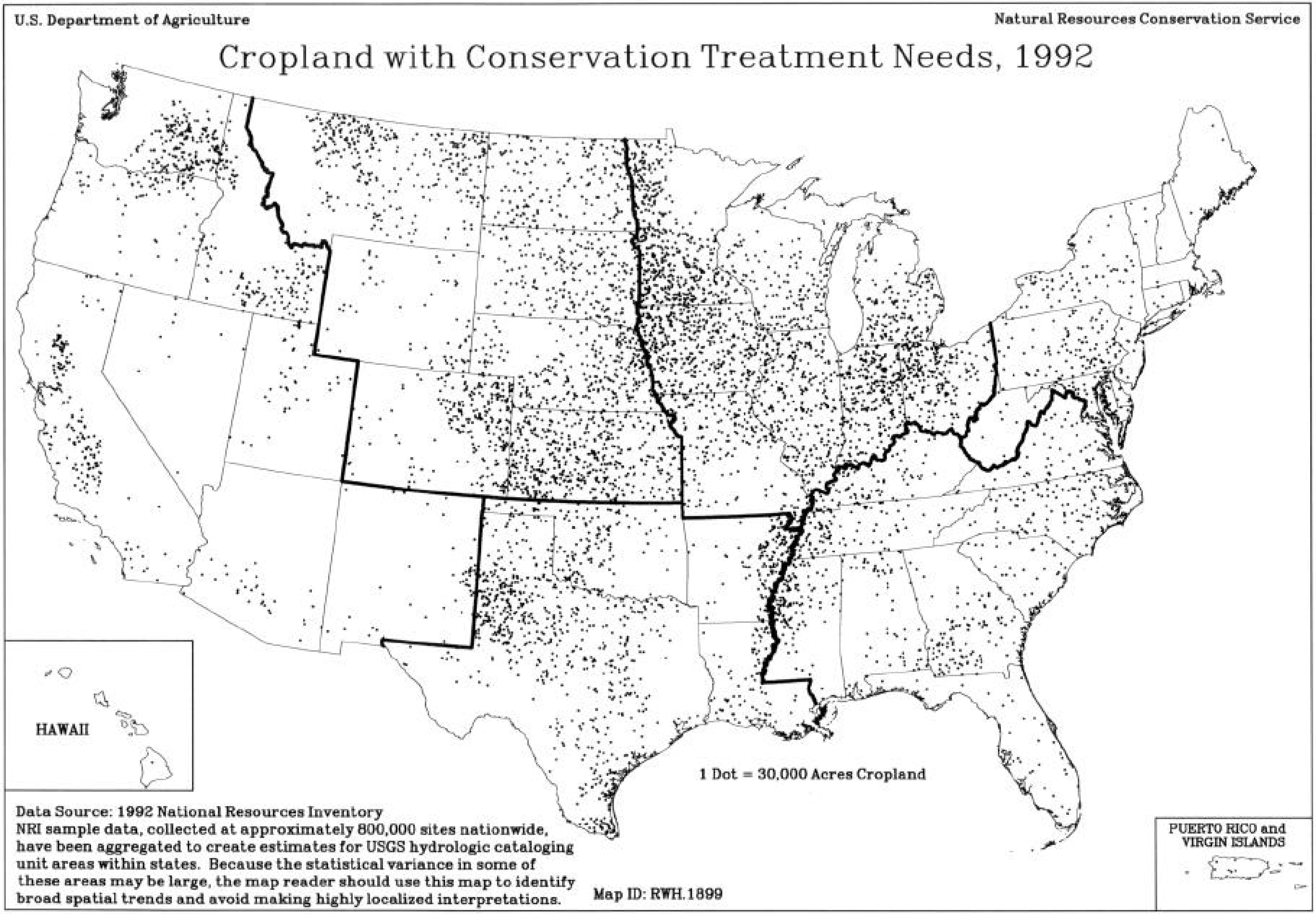

Figure 6-3. Map of cropland acres with conservation needs.

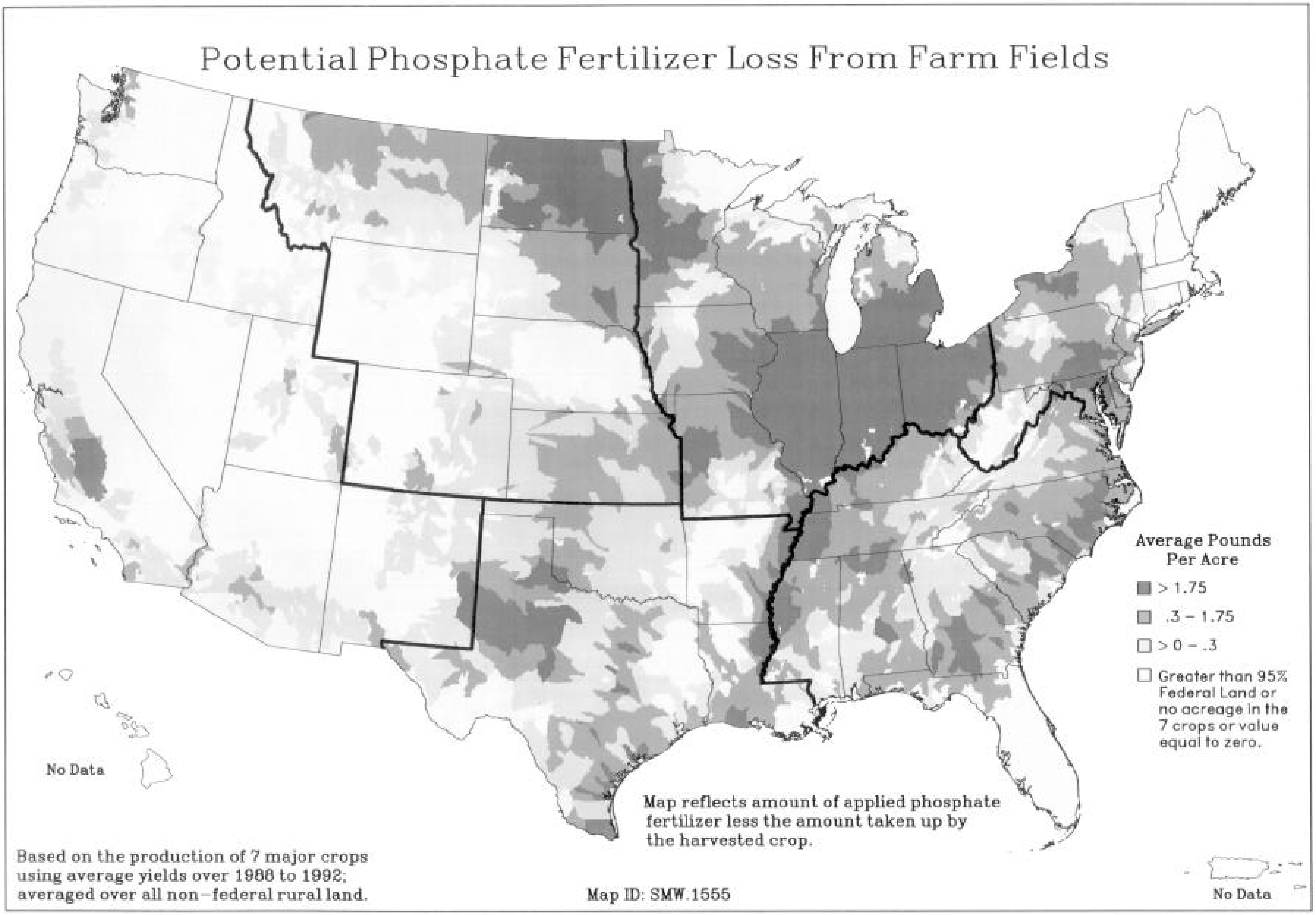

Figure 6-4. Map of potential fertilizer loss from farm fields.

Using this ecoregion approach, it was possible to identify specific farm production regions facing significant environmental risks. These risks are due to a combination of factors, including high-intensity agriculture, geologic/geographic conditions, and climate, all acting simultaneously to exacerbate the on-farm and off-site environmental impacts identified in the conceptual diagrams.

The major conclusion of the risk assessment was that agricultural production activities, if done in the absence of conservation technologies and practices, can have serious environmental impacts. However, the introduction, acceptance, and implementation of resource conservation technologies can significantly reduce these threats.

The risk assessment team found that the best solutions for environmentally stressed resources would be conservation measures applied in concerted, concentrated efforts in priority areas, with smaller scale efforts going to sectors outside priority areas. EQIP should employ a multiplicity of conservation measures, simultaneously and on a large scale. EQIP should address not only on-site problems, but also off-site unintended adverse consequences and cumulative effects. With this “fusillade” conservation approach, remedial actions will have greater effects than could occur otherwise. Over time, significant ecological improvement should be observed and downward environmental trends will move away from present “at risk” conditions.

The risk assessment also identified the need for additional data so that risk managers can be provided with a more complete analysis of all the environmental hazards related to agricultural production. Better environmental monitoring and evaluation tools need to be designed to assemble the actual effects of the application of conservation practices on the environment and on production agriculture.

Several sources of uncertainty also were identified during the analysis. One is associated with the interrelationships among all the resources of the ecosystem, not just the agricultural community. Time also adds a dimension of uncertainty. Long-term on- and off-farm effects may not be noticed until the resource has been so damaged that the productive capacity is beyond mitigation or restoration. A complete and quantitative environmental risk assessment may be difficult to perform for several reasons. The effects of applied resource conservation practices may not be seen immediately. What is done on one farm, tract, or ranch may register little to no effect, from a cumulative standpoint, on a watershed, hydrologic unit, or ecosystem. In addition, there is vast uncertainty associated with the role of agricultural production in landscape-scale ecological degradation.

6.3.1.2. *Conservation Reserve Program*

6.3.1.2.1. ***Background.*** CRP is authorized under subtitle D of Title XII of the Food Security Act of 1985, as amended. The statutory purpose of CRP is to assist owners and operators in conserving and improving soil, water, air, and wildlife resources on their farms and ranches by converting highly erodible and other environmentally sensitive cropland to permanent resource-conserving covers for 10 to 15 years. CRP is USDA's largest single conservation program. As many as 36.4 million acres of environmentally sensitive cropland have been enrolled in the program. Annual costs have reached nearly $2 billion, and the program has produced substantial soil erosion reduction, water quality improvement, and wildlife habitat enhancement benefits.

The assessment team acknowledged the difficulties associated with conducting a risk assessment on a nationwide scale. It stated that an assessment of the risks to the environment associated with agricultural production activities is highly complex. Activities undertaken for crop production form a very interdependent and complex system of cause-and-effect linkages, including feedback mechanisms and buffers, with the natural resource base. Often, long and varying time lags are associated with the occurrence of an event or activity and its impact on one or more elements of the resource base. Also, because of the large and diffuse set of cropping activities and farming operations, it is difficult to trace the impacts back to the original source. Further, similar environmental impacts can be caused by nonagricultural activities, and isolating the specific cause-and-impact relationships is often very difficult. Finally, other factors clearly outside the control of farm producers, such as weather and market forces, further complicate the diverse, complex, and dynamic set of environmental cause-and-effect relationships associated with agricultural cropland use. Because of this incredible complexity and diversity, it was extremely difficult to establish detailed and consistent databases that empirically describe the stressor-environmental component relationships and their impacts. These information shortfalls illustrate the uncertainties associated with supporting the hypotheses established in the assessment.

6.3.1.2.2. ***Problem formulation.*** As noted earlier in this chapter, the problem formulation section of the CRP risk assessment is functionally identical to that of the EQIP risk assessment (see Section 6.3.1.1.2). The only difference is that the CRP conceptual diagrams and accompanying discussion were limited to crop production activities and did not include livestock and grazing components. Pertinent conceptual diagrams developed by the EQIP risk assessment team were recreated for the CRP risk assessment.

6.3.1.2.3. ***Analysis of ecological effects.*** This section of the CRP risk assessment is also very similar to the analysis section of the EQIP risk assessment. Water impairment tables and data and pertinent NRI maps were incorporated. However, also included were maps of the continental United States (developed by the Economic Research Service) for discussion of air quality issues. Air quality was stipulated in the legislation of this program as a resource to be considered at risk. Populations affected by cropland wind erosion and EPA particulate matter (PM-10) nonattainment areas (July 1996) were represented on the maps.

The main difference between the CRP analysis and the EQIP analysis is the reference point for presentation of some of the data. The CRP analysis was based, in places, on evaluating the potential impacts as if there had not been a CRP in place for more than 10 years. For example, in a discussion of cropland erosion rates, the analysis stated, "Without enrollment of acreage in CRP, about 145 million acres would have eroded in excess of T and of the 2.14 billion tons of soil that would have eroded about 1.1 billion would have exceeded the sustainable T rate. With CRP enrollment, over one-third of the United States cropland, 131 million acres, is eroding at an average annual rate greater than T." The "T" rate is defined as the maximum erosion rate that can occur while allowing a soil to indefinitely sustain a high level of crop production.

6.3.1.2.4. ***Risk characterization.*** The assessment team intended to present information that would be useful in making decisions about the identity and location of the type of cropped acreage that should receive priority for enrollment in CRP. The principal contribution of the risk assessment was to present and combine information that will allow national-level policy makers to generally target the situations and areas where participation in the program is most likely to address environmental degradation. With this information, national-level policy makers can work with the States and localities in these areas to refine the application of CRP activities toward solutions to the environmental problems.

Time scales for natural resource recovery as a result of program actions were addressed in similar fashion to the EQIP risk assessment. However, recovery was estimated to occur much faster because of the almost complete cessation of the production activities creating the environmental stressors. A chronicle of uncertainties associated with a risk assessment of this type also was presented in similar fashion to that of the EQIP risk assessment.

Discussion centered on the topics of erosion-related impacts, wildlife habitat, fertilizer and pesticide application, and wetlands. Under erosion-related impacts, reference was made to the extent to which CRP has already contributed to erosion reduction and the impacts if CRP lands are returned to production. The amount (tons) of sediment delivered to water bodies as a result of erosion and of airborne soil from wind erosion was presented and discussed. The discussion of wildlife habitat was based on 10 geographic regions identified as priority areas in a 1995 U.S. Congress Office of Technology Assessment report. Additional agriculturally related geographic regions also were identified and discussed.

Patterns of fertilizer and pesticide use, areas for their potential impacts, and estimates of reductions in their use as a result of the previous CRP signups were presented. The same NRI maps associated with fertilizer and pesticide applications that were included in the analysis section of the EQIP risk assessment were presented in this risk characterization. Finally, a discussion of the location and acreage of cropped wetlands was presented.

In stark difference with the EQIP risk assessment, no direct recommendations to risk managers were made in this assessment.

6.3.2. Report on the Ecological Impacts of Nonindigenous Shrimp Viruses

This section presents an evaluation of potential shrimp virus impacts on wild shrimp populations in the Gulf of Mexico and southeastern U.S. Atlantic coastal waters. In a preliminary report to the Joint Subcommittee on Aquaculture, the Shrimp Virus Work Group (with members from the Department of Commerce, USDA, EPA, and Department of the Interior) used EPA's framework report (U.S. EPA, 1992) to conduct a preliminary analysis of the potential problem and to identify optional plans for performing a complete risk assessment. Although the risk assessment has not been performed, this case study does illustrate another way to use the framework report to aid risk managers (Shrimp Virus Work Group, 1997.)

6.3.2.1. *Background*

Nonindigenous shrimp viruses may be a threat to the sustainability of U.S. marine resources. New highly virulent diseases have been found in foreign shrimp aquaculture facilities, and the United States has greatly increased importation of shrimp produced in these facilities. The viruses pose no threat to human health, but there have been catastrophic disease outbreaks with 50% to 95% loss rates on U.S. shrimp farms as well as diseased shrimp found in commerce. Also, new information on the susceptibility of wild shrimp and other crustaceans to the virus has come to light. Shrimp harvesting and processing in the United States is a $3-billion-a-year industry. As a result, there have been calls for a risk assessment of the potential threat of the viruses to marine resources.

The Shrimp Virus Work Group was formed by the Joint Subcommittee on Aquaculture to assess potential risks. The work group used the risk assessment framework to organize existing information, determine the need for a formal assessment, and formulate options for performing an assessment. The problem formulation step was used to develop a conceptual model, develop an overview of economic impacts, list the potential effects of the viruses on shrimp and other aquatic species, summarize the basic life history of shrimp, identify potential stressors affecting the shrimp population, and identify potential pathways for the exposure of wild shrimp to the viruses.

After using the framework as a tool for organizing information, the work group proposed several options for doing an assessment. It also recommended that a formal ecological risk assessment be done to provide information needed to address international trade issues, national and State regulatory obligations, and the needs of industry, environmental groups, and the public.

6.3.2.2. ***Management Goals***

The process was initiated with the risk assessors and managers agreeing on the scope of the potential assessment and setting management goals. The goal of the analysis was to provide information to help prevent the establishment of new disease-causing viruses in wild populations of shrimp in the Gulf of Mexico and southeastern U.S. Atlantic coastal waters, while minimizing possible impacts on shrimp importation, processing, and aquaculture operations.

6.3.2.3. ***Problem Formulation***

The work group performed the three steps of problem formulation: (1) define assessment endpoints, (2) develop the conceptual model, and (3) develop an analysis plan.

6.3.2.3.1. ***Assessment endpoints*****.** In identifying potential assessment endpoints, the work group focused on linking the management goal with the environmental values to be protected. The primary assessment endpoint selected is the survival, growth, and reproduction of wild penaeid shrimp populations in the Gulf of Mexico and southeastern U.S. Atlantic coastal waters. The focus was on the wild penaeid shrimp in and around the Gulf because of the societal and ecological importance of these shrimp populations and their known susceptibility to the stressors in question (the viruses).

A secondary endpoint is the ecological structure and function of the coast and near-shore marine communities as they affect wild penaeid shrimp populations. This endpoint was selected because the shrimp population cannot be protected without considering the ecological system it inhabits. For example, other crustaceans such as copepods, amphipods, and crabs share habitat with the shrimp during key stages of the shrimp life cycle. The other crustaceans may be alternative hosts for the viruses and serve as a potential reservoir and vector for transmission.

6.3.2.3.2. ***Conceptual models*****.** Developing the conceptual model aids the risk assessor in formulating the risk hypotheses that will be evaluated during the assessment. The modeling process was used by the work group to identify the most significant linkages among human activities, stressors, and the assessment endpoints.

Diagrams were used to communicate important pathways in a clear and concise way and to identify major sources of uncertainty. The two major pathways for the imported viruses to enter the domestic ecosystems were identified as aquaculture and shrimp processing. Sources of aquaculture infection include contaminated feed, broad stock, transport vehicles and containers, and bird and animal transport. The aquaculture shrimp can then infect native populations through escapement, pond flooding, sediment and solid waste disposal, etc. Processing plants are generally located on waterways, and processing wastes are generally discarded directly into the adjacent water. Other sources of infection include infected bait shrimp, ship ballast water, nonshrimp translocated animals, and natural spread.

The modeling process considered a variety of stressors but focused on four particularly virulent species of nonindigenous viruses found in imported shrimp but not yet detected in native U.S. shrimp. Other anthropogenic stressors such as harvesting, contaminants (e.g., organic matter that lowers dissolved oxygen), and habitat destruction also were considered in the model. Environmental stressors, including temperature, salinity, and predation, were considered as well because they affect shrimp population dynamics. Shrimp exposure to these stressors was evaluated at the various stages of the shrimp's life cycle.

Direct and indirect viral effects included in the model were individual shrimp mortality and population effects, as well as effects on other species and indirect ecological effects. The indirect ecological effects could include changes in ecological structure (species composition) and ecological function (predator/prey relationships, competition for niches and habitat, and nutrient cycling).

The modeling process confirmed the complexity of the socioeconomic and natural system being assessed and revealed numerous data gaps. Twenty-seven significant data gaps were identified, and most of these will not be easily filled. Examples include (1) shrimp population models that adequately explain variability of wild populations; (2) distribution and effects of viruses on nonshrimp organisms; (3) distribution and genetic diversity of offshore populations; (4) concentrations, frequency, duration, location, and environmental media of the viruses; (5) evaluation of the effects of interactions among multiple stressors; and (6) number and size of U.S. aquaculture operations in relation to receiving waters harboring native shrimp.

6.3.2.3.3. ***Analysis plan*****.** The analysis plan evaluates risk hypotheses and summarizes the assessment design, data needs, measures, and methods for conducting the analysis phase of the risk assessment. In a complex assessment such as the potential shrimp assessment, the plan should identify (1) the pathways most important to the exposure and specify the relationships most critical to evaluating risks; (2) the measures of effects, exposure, and ecosystem characteristics to evaluate; and (3) how to address data gaps. In this case study, the work group did not perform a formal assessment. Instead, it laid out a brief plan with options for doing an assessment in the future.

6.3.2.4. *Analysis and Risk Characterization*

This phase consists of two activities: characterization of exposure and characterization of risk. The work group identified 15 considerations that should be included in any future exposure characterization and 9 considerations for a risk characterization. Neither set of characterizations has been done.

The risk characterization is the final phase of the risk assessment. Although the work group did not perform this phase, it indicated that confidence in the results of a future assessment could be strengthened if there were agreement between several different lines of evidence. It recommended pursuing several lines of evidence on exposure pathways: (1) laboratory bioassay; (2) viral outbreaks in aquaculture; (3) effects, or lack of effects, of viral exposure in wild populations; and (4) predicted effects based on exposure scenarios.

6.3.2.5. *Summary*

The work group's summary focused on information gathered on exposure and ecological risks that could be assessed from available information, and on its list of data gaps and research needs. Two key pieces of information were that some countries knowingly export infected shrimp, and that despite extensive efforts by the U.S. Marine Shrimp Farm Program, State agencies, and producers to prevent viral outbreaks, there have been numerous disease outbreaks on U.S. shrimp farms in recent years. Therefore, there is reason to take seriously the possibility of the wild population becoming infected.

The work group concluded that proceeding with a full risk assessment at this time would result in a high level of uncertainty because of the many data gaps. However, there may not be time to do the research needed to reduce the data gaps because of the nature of the potential risk. The work group identified three assessment options: a quick qualitative risk assessment, a longer term quantitative risk assessment, and a tiered assessment. The tiered assessment would start with the qualitative assessment and then refine it as data become available.

6.4. RISK ASSESSMENT METHODOLOGY DEVELOPMENT

The shrimp virus case study demonstrates that the framework report (U.S. EPA, 1992) is useful even for preliminary presentation and identification of a potential problem. The available data can be arranged in such a way that formal risk assessment follows in a prescribed and logical fashion. In the case study report, information and data needs were enumerated, and scenarios for conducting the assessment under different sets of available data were discussed. However, this case study is an example of the single-stressor (virus types), single-receptor (wild shrimp species) risk assessment that was fully developed in EPA's framework and guidelines reports (U.S. EPA, 1992, 1996).

EPA's framework and guidelines reports provided a basic methodology for developing the risk assessments for the conservation programs. However, the reports did not fully develop a protocol for conducting risk assessment on multiple physical and chemical stressors at the scope and scale necessary for these programs. The methodology needs to be modified so that risk assessment guidelines can be developed for future conservation and other agroecosystem programs. The EQIP and CRP risk assessments focused heavily on the problem formulation phase of the process. Quantitative analysis of ecological effects and exposure was beyond the scope of the assessments, given the time and financial resource constraints. It is unlikely that there will be sufficient data, time, or finances in the near future to conduct such an empirical analysis for these broad-based, nationwide environmental programs. The immediate goals should be:

- Develop a basic methodology and set of guidelines for developing agroecosystem risk assessment.

- Identify sources of available data useful for agroecosystem risk assessments.

- Develop a process for directing research activities at governmental or nongovernmental institutions for the production or collection of relevant environmental data.

- Develop a process for directing research activities at governmental or nongovernmental institutions for the development of analytical models to support use of data in ecological risk assessment.

- Encourage interagency and multidisciplinary collaborative efforts in data collection, baseline assessment, and environmental monitoring to support risk assessment.

- Encourage interagency and multidisciplinary collaborative efforts in conducting ecological risk assessments on a landscape scale.

6.5. RISK MANAGEMENT

The challenge to government agencies that conduct risk assessment on agricultural production is to develop an iterative process early in regulatory development. This includes identifying when risk assessment will be required, clearly identifying risk management objectives, and establishing an iterative process between risk assessment and risk management for the course of program development. Agroecosystem risk assessment is a new requirement for USDA, and it is not possible at this early date to determine how it will affect future regulatory development. It will also take time to determine whether risk assessment will affect future risk management activities based on annual program evaluation. The predicted potential benefits from the required analyses of the National Environmental Policy Act have suffered from a process that has resulted in the preparation of environmental assessments and environmental impact statements very late in regulatory development. All these tools were designed to aid in the decision making that occurs during regulatory development, and they are not used to their fullest when approached in this way.

It is necessary that there be clearly identified strategies for using these tools so that programs can minimize adverse ecological impacts while achieving other agricultural goals. Arguably, using an ecological risk assessment framework in developing agricultural strategies would help improve ecological protection. However, ecological risk assessments have had only limited and recent use in assessing new policies, technologies, and production systems. Consequently, it is not clear how significant the impact will be on public agricultural decision making.

Risk management must play a role in the development and use of risk assessments if the intent is for risk assessment to aid in the decision-making process of regulatory development:

- Private as well as public risk managers will need to participate in the assessment planning process because so many groups of stakeholders are associated with agriculture.

- Risk managers will need to make decisions balancing the need for a timely, scientifically sound and credible risk assessment to support decision making with the time commitment and monetary investment required to remove data gaps and reduce uncertainty in the assessment.

- Risk managers will have to balance often-conflicting goals because of the broad geographical scope, interdisciplinary complexity, and different statutory guidelines of agencies participating in the assessments. Implementing and regulatory agencies, Federal, State, and local governments, and public and private sector activities frequently have different missions and goals that must be reconciled if assessments are to be useful and effective.

6.6. NEXT STEPS

The U.S. Department of Agriculture may wish to address the following recommendations to further incorporate ecological risk assessment in the management of agricultural ecosystems.

- Ecological risk assessments are a relatively new tool in agriculture. Promoting the use of this tool will require a sustained promotional and training program for risk assessors and managers in both the public and private sectors.

- Reducing data gaps will require some adjustments in research priorities to put more emphasis on understanding the structural and functional relationships of agroecosystems.

- Statutes, regulations, and policies of the agencies involved in ecological risk assessments should be reviewed to identify and remove any barriers that limit the effectiveness of interagency assessments, particularly when they involve operating and enforcement agencies. Such barriers could result from conflicting requirements for assessment scope, data, and methodologies; standards of review; and the role of the assessment in the decision-making process.

6.7. REFERENCES

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7. ENDANGERED/THREATENED SPECIES

7.1. SUMMARY

The determination of the impact of physical, biological, and chemical stressors on the survival of a given species fits well within the framework for ecological risk assessment. The National Research Council (NRC) report on “Science and the Endangered Species Act” (NRC, 1995a) states that “the concept of risk is central to the implementation of the Endangered Species Act.” It calls for enhanced use of biologically explicit quantitative models and evaluation of multiple stressors for risk assessment when evaluating endangered and threatened populations. The evaluation of the likelihood of extinction of a species fits within the definition of risk assessment. However, this chapter focuses on the analysis phase of an ecological risk assessment; the full adaptation of the ecological risk assessment framework to this topic has not yet been done.

The other phases of ecological risk assessment are not as clearly addressed in this chapter. Problem formulation could be considered to be largely statute driven, with the question “What are we trying to protect?” clearly stated to be endangered and threatened species and the means to conserve the ecosystem upon which they depend. In the risk characterization, addressed in part in Section 7.3.1.3, the likelihood of extinction within a given time frame and the uncertainties of the risk of extinction are discussed. The impacts of future events are also considered.

This chapter focuses on the use of specific modeling tools for estimating the risks of extinction of endangered or threatened populations. Population biology parameters that influence the probability of extinction include random demographic or environmental changes, loss of adaptive variation, environmental catastrophes, accumulation of deleterious genetic factors, and habitat fragmentation. The effects are determined by collection of scientific and commercial data on population numbers and rate of decline. Population models are used to produce information on population stability, time to extinction, and even time to recovery—if the stressors are removed. Life history models can identify stages of an animals life where it is most susceptible to impacts from stressors.

A sound scientific process and peer review are critical to ensure that a consensus scientific product is put forward to decision makers. It is clear that various components of ecological risk assessment are used in listing of endangered and threatened species. Whether it will be further applied will depend on the scientists or managers wanting additional information such as likelihood and consequences from population models, evaluating uncertainty, or conducting sensitivity analysis.

7.2. THE ENDANGERED SPECIES ACT OF 1973

When the Endangered Species Act (ESA) was passed in 1973, it represented a bipartisan response to the decline of many wildlife species around the world. The ESA is regarded as one of the most comprehensive wildlife conservation laws in the world. Its purposes are to conserve the ecosystems upon which endangered and threatened species depend and to conserve and recover listed species. Under the law, species may be listed as either "endangered" or "threatened." Endangered means that a species is in danger of extinction throughout all or a significant portion of its range. Threatened means that a species is likely to become endangered within the foreseeable future. All species of plants and animals, except pest insects, are eligible for listing as endangered or threatened.

As of April 30, 1997, 1,081 U.S. species were listed, of which 447 were animals. The list includes both U.S. and foreign species and covers mammals, birds, reptiles, fishes, snails, clams/mussels, crustaceans, insects, arachnids, and plants. Groups with the most listed species are (in order) plants, birds, fishes, mammals, and clams/mussels.

The law is administered by the U.S. Fish and Wildlife Service of the U.S. Department of the Interior and the National Marine Fisheries Service of the U.S. Department of Commerce. The U.S. Fish and Wildlife Service has primary responsibility for terrestrial and freshwater organisms, while the National Marine Fisheries Service's responsibilities concern mainly marine species such as salmon and whales.

The 1973 ESA replaced earlier laws enacted in 1966 and 1969 that provided for a list of endangered species but gave them little meaningful protection. The 1973 law has been reauthorized seven times and amended on several occasions, most recently in 1988. The ESA was due for reauthorization again in 1993, but legislation to reauthorize it has not yet been enacted. The ESA has continued to receive appropriations while Congress considers reauthorization, allowing conservation actions for endangered species to continue. The ESA is a complex law with a great deal of built-in flexibility. Some basics of the law, including key terms, are given in Sections 7.2.1 through 7.2.1.11.

7.2.1. Purpose

When Congress passed the ESA in 1973, it recognized that many of our Nation's native plants and animals were in danger of becoming extinct. They further expressed that our rich natural heritage was of "esthetic, ecological, educational, recreational, and scientific value to our Nation and its people." The purposes of the ESA are to protect these endangered and threatened species and to provide a means to conserve the ecosystems upon which they depend.

7.2.2. Listing

Species are listed on the basis of the best scientific and commercial data available. Listings are made solely on the basis of the species' biological status and threats to its existence. The U.S. Fish and Wildlife Service bases all listings on sound science and uses peer review to ensure the accuracy of the best available data.

7.2.3. Species

The definition of "species" includes any subspecies of fish or wildlife or plants, and *distinct population segments of vertebrate* fish or wildlife species. This allows for populations of vertebrate animals to be protected in regions of the country where they are in trouble without requiring protection in areas where they are doing well. For example, bald eagles are listed as threatened in the lower 48 States, but are not listed at all in Alaska where they are more numerous. The Clinton Administration has issued new guidelines to clarify the definition of "distinct population segments" under the ESA.

7.2.4. Candidate Species

The U.S. Fish and Wildlife Service maintains a list of "candidate" species. These are species for which the Service has enough information to warrant proposing them for listing as endangered or threatened but that have not yet been proposed for listing. The Service works with States and private partners to carry out conservation actions for candidate species to prevent their further decline and possibly eliminate the need to list them as endangered or threatened. As of April 30, 1997, there were 182 candidate species.

7.2.5. Recovery

The law's ultimate goal is to "recover" species so they no longer need protection under the ESA. The ESA provides for recovery plans to be developed, describing the steps needed to restore a species to health. As of April 30, 1997, 653 of the listed U.S. species under the Service's jurisdiction had approved recovery plans. Appropriate public and private agencies and institutions and other qualified persons assist in the development and implementation of recovery plans. Recovery teams may be appointed to develop and implement recovery plans. The Clinton Administration has issued new guidelines requiring the involvement of interested "stakeholders" in recovery plans.

7.2.6. Consultation

The ESA requires Federal agencies to consult with the Service to ensure that the actions they authorize, fund, or carry out will not jeopardize listed species. In the relatively few cases where the Service has determined that the proposed action would jeopardize a species, it must issue a "biological opinion" offering "reasonable and prudent alternatives" about how the proposed action could be modified to avoid jeopardy to listed species. It is rare that projects are withdrawn or terminated because of jeopardy to listed species.

7.2.7. Critical Habitat

The ESA provides for designation of "critical habitat" for listed species. Critical habitat includes geographical areas "on which are found those physical or biological features essential to the conservation of the species and which may require special management considerations or protection." Critical habitat may include areas not occupied by the species at the time of listing but that are essential to the conservation of the species. Critical habitat designations affect only Federal agency actions or federally funded activities.

7.2.8. International Species

The ESA is the law that implements U.S. participation in the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), a 130-nation agreement designed to prevent species from becoming endangered or extinct because of international trade. The law prohibits trade in listed species except under CITES permits.

7.2.9. Exemptions

The law provides a process for exempting development projects from the restrictions of the ESA. This process permits completion of projects that have been determined to jeopardize the survival of a listed species, if a Cabinet-level Endangered Species Committee decides the benefits of the project clearly outweigh the benefits of conserving a species. Since its creation in 1978, the Committee has been called on only three times to make this decision.

7.2.10. Habitat Conservation Plans

This provision of the ESA is designed to relieve restrictions on private landowners who want to develop land inhabited by endangered species. Private landowners who develop and implement an approved "habitat conservation plan" that provides for conservation of the species can receive an "incidental take permit" that allows their development project to go forward.

7.2.11. Definition of "Take"

Section 9 of the ESA makes it unlawful for a person to "take" a listed species. The ESA states, "The term take means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect or attempt to engage in any such conduct." The Secretary of the Interior, through regulations, has defined the term "harm" in this passage as "an act which actually kills or injures wildlife. Such act may include significant habitat modification or degradation where it actually kills or injures wildlife by significantly impairing essential behavior patterns, including breeding, feeding, or sheltering." This regulation has been in place since 1975 and was amended in 1991 to emphasize that only actual death or injury of a protected animal would constitute a legal violation.

7.3. ESTIMATING RISK

Sections 7.3 and 7.4 represent the state of the practice on the use of risk assessment in the ESA. The sections were taken, with permission from the National Research Council (NRC), from Chapter 7 of the NRC report " Science and the Endangered Species Act" (NRC, 1995a). The sections have been modified in some places as necessary for clarity within this document.

The concept of risk is central to the implementation of the Endangered Species Act. The National Academy of Sciences (NAS) committee was asked to review the role of risk in decisions made under the act, review whether different levels of risk apply to different types of decisions made under the act, and identify practical methods for assessing risk.

Risk is the probability that something (usually a bad outcome) will occur. *Risk assessment* aims to estimate the likelihood of a particular (usually bad) outcome occurring. *Risk management* is an integrating framework that assesses the likelihood of bad outcomes and analyzes ways to minimize the risk of bad outcomes, or at least to respond appropriately if they occur. Many risk assessments follow the framework developed by the National Research Council to apply to human health (NRC, 1983); an example of a specific risk assessment framework is the one developed by EPA's Risk Assessment Forum (U.S. EPA, 1992), which tracks patterns of exposure to harmful substances and responses of ecological systems to these exposures. The sometimes confusing terminology of risk assessment and some of the issues in applying risk assessment to ecological systems were described by Policansky (1993); further examples were discussed by the National Research Council (1993).

The main challenges involved in the implementation of the ESA are the risk of extinction and the risk management issues associated with unnecessary expenditures or curtailment of land use in the face of substantial uncertainties about the accuracy of estimated risks of extinction and about future events. Here we consider the problem of estimating the risk of extinction and the limitations of our current ability to estimate this risk. Models are an important tool for analyzing the consequences of complex processes, because intuition is often not reliable. In some cases, the predictions of the models are not precise because information is lacking or because the underlying processes are not fully understood. They are valuable as guides to research and as tools for analyzing the comparative effects of various environmental and management scenarios.

7.3.1. Estimating the Risk of Extinction

Since the inception of the ESA, there have been enough developments in conservation biology, population genetics, and ecological theory that substantial scientific input can be used in the listing and recovery-planning processes. The following text synthesizes and evaluates the various approaches and conclusions that have emerged from recent attempts to understand the vulnerability of small populations to extinction. The material focuses on random changes in population sizes and in their structure, changes in genetic variability, environmental fluctuations, and habitat fragmentation. Additional theoretical and field research is needed to resolve or reduce uncertainties, but existing analyses give insight into the relative magnitude and possible scaling of various influential factors in the extinction process. More thorough and technical reviews were provided by Dennis et al. (1991), Thompson (1991), and Burgman et al. (1992).

7.3.1.1. *Sources of Risk*

Habitat loss, effects of introduced species and, in some cases, overharvesting are almost always the ultimate causes of species extinction. Decline of populations to a low density makes them vulnerable to chance events and sets into play the extinction risks outlined below. When conditions have deteriorated to the point that a wild population cannot maintain a positive growth rate, no sophisticated risk analysis is required to tell us that extinction is inevitable without human intervention. Our attention here is focused on cases in which a population with a positive capacity for growth in an average year is still vulnerable to chance events that cause short-term excursions to low densities. Limitations of these approaches are discussed in Section 7.3.1.2.

7.3.1.1.1. *Random demographic changes*. Demographic features, such as family size, sex, and age at mortality vary naturally among individuals. In populations containing more than about 100 individuals, individual variation averages out and has little effect on the dynamics of population growth. However, in small populations, random variation in demographic factors can occasionally reach such an extreme state that extinction is certain. This can arise, for example, if all members of one sex die before reaching maturity or if all progeny are of the same sex, as was the case with the dusky seaside sparrow (*Ammodramus maritimus nigrescens*) after loss of habitat led to its population decline.

Substantial effort has been expended to develop general models for predicting the risk to small populations of extinction due to demographic stochasticity. Several assumptions must be made about the ways in which populations grow, in particular about the way population growth rates respond to density. From the standpoint of an endangered species, the simplest conceivable model assumes that the population has been pushed to its limits—resources (habitat and food availability) have become so scarce that, on average, the expected number of births in an interval is the same as the expected number of deaths. In this case, with individual births and deaths being random, the mean time to extinction for a population starting with N individuals is simply N generations (Leigh, 1981), that is, the time to extinction increases linearly with the population size.

A more common situation is one in which resources are sufficient to support an average positive population growth when the population density is below a threshold. Due to chance, the actual growth rate in any generation will deviate somewhat from its expected value, and in the rare event that the cumulative growth rate realized over several consecutive generations is sufficiently negative, the population size will be reduced to zero (i.e., extinction will occur).[3]

All the demographic models discussed in this section assume that all members of the population are functionally identical. There is no variation based on age or sex; individuals are assumed to be identical with respect to reproductive and mortality rates. Thus, strictly speaking, the results apply best to short-lived asexual organisms or to hermaphrodites that synchronously reproduce toward the end of their life, as do many annual plants and some invertebrates. Models incorporating age structure, which are appropriate for vertebrates, require information on the mean and variance of age-specific mortality and fecundity schedules (Lande and Orzack, 1988; Tuljapurkar, 1989), information that is limited for even the best-studied species in nature.

For species with separate sexes (most vertebrates and many other organisms), another source of demographic stochasticity can lead to extinction. When the population is small, there is some probability that all of the offspring produced in a generation will be of the same sex. For a population at size N, the probability of this event is $2(0.5^N)$, and the reciprocal of this quantity, 2^{N-1}, gives the mean extinction time if sex-ratio fluctuations are the only source of extinction.[4]

Unless the population is very small, sex-ratio fluctuations alone are unlikely to cause extinction. However, if the population birth rate is a function of the number of females, as is usually the case, sex-ratio fluctuations will generate fluctuations in the population birth rate. This

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[3]With this type of model, the mean time to extinction increases exponentially with the product of the expected population growth rate at low density, r, and the population carrying capacity, K, where K can be viewed as the number of individuals that a reserve can sustain at stable density.

[4]The derivation of this relationship is as follows: the probability that an individual is male is 0.5, and the probability of all individuals being male in a sample of N individuals is $0.5N$. Thus, the probability that the sample consists of either all males or all females is $2(0.5N)$, in which case the population goes extinct through its inability to reproduce.

type of synergism can reduce the mean survival time of a population by orders of magnitude relative to expectations from models that ignore sex (Gabriel and Burger, 1992). For example, if the number of adults the environment can support (K) is less than 25 individuals or so, the mean time to extinction can be as low as 100 generations, even when the maximum rate of population growth is quite high.

The preceding results apply to populations for which the initial density is at the carrying capacity. When a species is recognized as endangered, however, it usually has declined dramatically, at which point the recovery goal is to increase the population density to some higher sustainable level. Richter-Dyn and Goel (1972) developed a general solution for the mean extinction time starting from an arbitrary density, again assuming that random fluctuations in birth and death rates are the only source of extinction risk. Their model is quite flexible in that it allows for any pattern of density-dependence in the birth and death rates.

7.3.1.1.2. *Random environmental changes*. Demographic stochasticity becomes less important as the density of a population increases and individual differences average out; however, this is not the case when temporal variation in an exogenous factor, such as the weather, influences the reproductive or survival rates of all individuals in a population simultaneously. Environmental fluctuations influence different individuals to different degrees, but to this point, the theory has only been developed for the situation in which all individuals respond in an identical manner to environmental change. The discussion below expands on the preceding section by incorporating environmental as well as demographic stochasticity.

Most models consider the population to be growing with an average growth rate of r per capita per year, and variance in this rate among generations, V_e, is due to environmental fluctuations. Typically, it is assumed that the variance is independent of population size and that there is no correlation between the state of the environment in one generation and the next. Such assumptions are probably rarely fulfilled in natural populations, and violations of them would most likely enhance the risk of extinction, as when generations of poor growth conditions tend to be clustered. These caveats aside, a general prediction of models that incorporate environmental stochasticity is that the mean extinction time is determined by the ratio r/V_e—the higher the average growth rate and the lower the variance, the longer the population is likely to survive. Moreover, the rate of increase of population longevity with increasing K is much slower when environmental stochasticity is present than when demographic stochasticity operates alone. Depending on the magnitude of V_e relative to r, even populations with several hundreds or thousands of individuals can be vulnerable to environmental stochasticity.

The theory just discussed treats environmental variation as a factor that drives variation in the intrinsic rate of population growth, r. Although this is certainly likely to be true in many cases, environmental factors can also define the carrying capacity of a population. Thus, an alternative approach to the treatment of environmental stochasticity is to let K, as well as r, vary. Variation in K alone cannot cause extinction, unless the carrying capacity actually declines below zero. However, K puts a ceiling on the attainable population size, and bottlenecks in K can magnify the effects of demographic stochasticity by enhancing the variation in the population growth rate due to the smaller sample of reproductive adults. Only limited work has been done on these issues (see Roughgarden, 1975; Slatkin, 1978).

7.3.1.1.3. *Catastrophes*. Catastrophes are extreme forms of environmental variation that suddenly and unpredictably reduce the population size. To the extent that these events are determined by the weather, lightning fires, epidemics, etc., human intervention can do little to influence their frequency. However, because catastrophes affect most members of a population to more or less the same extent, it is clear that, on the basis of chance alone, larger populations will have an increased likelihood of some individuals surviving this kind of event.

Hanson and Tuckwell (1981) and Lande (1993) have considered the time to extinction for populations exposed to randomly occurring events, each reducing the population size to a constant fraction of its current size, the former using a logistic and the latter an exponential growth model. In these models, there is no demographic or environmental stochasticity of the kinds noted above. Rather, extinction occurs only when, by chance, a cluster of catastrophes occurs. Provided the long-run growth rate is positive, the mean extinction time increases exponentially with the carrying capacity under this model, with the rate of scaling increasing with the frequency of occurrence and magnitude of catastrophes. Assuming catastrophes act locally, spatial subdivision of a species provides a simple means of protection against extinction caused by devastating events.

7.3.1.1.4. *Accumulation of deleterious genetic factors*. The reduction of a population to a low density has several negative genetic consequences that can magnify vulnerability to extinction. Most species harbor far more than enough deleterious recessive genes to kill individuals if they were to become completely homozygous (Simmons and Crow, 1977; Charlesworth and Charlesworth, 1987; Ralls et al., 1988; Hedrick and Miller, 1992). This large genetic load is essentially unavoidable because it is maintained by a deleterious mutation rate of approximately one per individual per generation (Mukai, 1979; Houle et al., 1992). In large populations, deleterious genes, particularly lethal genes, have only minor consequences—the frequencies of most deleterious genes are kept low by natural selection, and their expression is minimal because they are usually masked in the heterozygous state. This situation can change dramatically in small populations. During bottlenecks in population size, mildly deleterious genes, previously kept at low frequency by natural selection, can rise to high frequency by chance. When these genes become completely fixed (reach a frequency of 100%), a permanent reduction in population fitness results.[5]

Although some deleterious genes may be purged from a population early in a population bottleneck (Templeton and Read, 1984), the continued maintenance of a population at small size can only magnify the long-term accumulation of mildly deleterious genes. As noted above, deleterious mutations arise at a rate of about one per individual per generation. Provided the individual selective effects of these genes are small (on the order of l/4 N_e or less), they will accumulate at the genomic mutation rate, causing a decline in mean fitness of approximately s per generation (Lynch, 1994). Thus, $s = 0.025$ (as described in footnote 3), a small population would be expected to experience a roughly 2.5% decline in fitness per generation due to deleterious mutations alone, and the rate of mutation accumulation declines with increasing population size. If the effective population size (N_e) is greater than 1,000, mutation accumulation is essentially halted for time scales relevant to endangered species management. However, if the accumulation of deleterious genes reaches the point at which the net reproductive rate of individuals is less than l, the population is incapable of replacing itself. At this point, the population size begins to decline, and random drift progressively overwhelms natural selection; consequently, decline in fitness accelerates through the accumulation of deleterious mutations. This synergism, whereby the rate of decline in fitness increases with the accumulation of deleterious genes, has been referred to as a "mutational meltdown" (Lynch and Gabriel, 1990; Lynch et al., 1993) and, once initiated, can lead to rapid extinction.

7.3.1.1.5. *Loss of adaptive variation within populations*. Most populations, even those undisturbed by human activity, are exposed regularly to temporal and spatial variation in physical and biotic features of the environment. In principle, some species can cope with such selective challenges by simply migrating to suitable habitat (Pease et al., 1989). However, endangered species often live in highly fragmented habitats with inhospitable barriers; migration might not be

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[5]Roughly speaking, if N_e is the effective number of breeding adults and s is the selection intensity opposing a deleterious gene in the homozygous state, then selection is ineffective if $4N_e s < 1$. Typically, because of high variance in family size, the effective population size is one-third to one-tenth the actual number of breeding adults (Heywood, 1986; Briscoe et al., 1992). Thus, as a first approximation, if the number of breeding adults is less than $2/s$, natural selection will be essentially incapable of eliminating a deleterious gene—its future frequency will be governed by chance, with the probability of fixation being equal to the initial frequency. The current wisdom is that s for an average mutation is approximately 0.025 (Simmons and Crow, 1977; Houle et al., 1992). Noting that $2/0.025 = 80$, this implies that a substantial number of the rare deleterious genes in a population can drift to high frequency if the number of breeding adults is reduced to 100 or fewer individuals for a prolonged period.

an option. This leaves adaptive evolutionary change, which requires heritable genetic variation, as the primary means of responding to selective challenges (habitat degradation, global climatic change, species introductions, etc.) that threaten species with extinction.

Consider a population that is faced with a gradual change in a critical environmental factor, such as temperature, humidity, or prey size. If the rate of change is sufficiently slow and the amount of genetic variance for the relevant characters in the population sufficiently high, then the population will be able to evolve slowly in response to the environmental change, without a major reduction in population size. If the rate of environmental change is too high, the selective load (reduced viability and fecundity) on the population will exceed the population's capacity to maintain a positive rate of growth, and although the population might respond evolutionarily, it will become extinct in the process. Thus, for any population, there must be a critical rate of environmental change that allows the population to evolve just fast enough to maintain a stable size. Lynch and Lande (1993) showed that this critical rate is directly proportional to the genetic variance for the character upon which selection is acting.

Several factors influence standing levels of genetic variation for characters associated with morphology, physiology, and behavior. Most forms of natural selection cause a reduction in the genetic variance by eliminating extreme genotypes, the exact amount depending on the intensity of selection. Small populations also lose an expected $1/2N_e$ of their genetic variance each generation because of the chance loss of some genes by random genetic drift. Mutation adds genetic variation to each generation of a population. When populations are kept at a constant size and under constant selective pressures, they ultimately evolve an equilibrium level of genetic variance, at which point the loss due to selection and drift is balanced by mutational input.

For large populations, the magnitude of this equilibrium variation is debatable, because it depends on the gametic mutation rate and the distribution of mutational effects, neither of which are very well understood (Barton and Turelli, 1989). However, for populations with effective sizes of a few hundred or fewer individuals, the expected amount of variation for a typical quantitative character is nearly independent of the strength of selection and proportional to the product of the effective population size and the rate of mutational input of variation (Bürger et al., 1989; Foley, 1992). This implies that for populations containing hundreds or fewer individuals, the rate of environmental change that can be sustained for a prolonged period is directly proportional to the effective population size. In other words, a doubling in population size effectively doubles the evolutionary potential of the population.

Some attempts to identify a critical minimum population size for captive populations from a genetic perspective have focused on goals such as the maintenance of 90% of the genetic variation present in the ancestral (predisturbance) population for 200 years (Franklin, 1980; Soule et al., 1986). Goals of this nature take into consideration the fact that populations that are dwindling in size cannot be in equilibrium. However, these goals are rather arbitrary with respect to choice of acceptable loss and time span. For long-term planning, an alternative approach is to consider that above a certain effective population size, the dynamics of genetic variation are influenced predominantly by selection and mutation, so that any further increase in the effective population size would not significantly influence the amount of genetic variation maintained in the population. Based on the above arguments and because the effective population size is generally several-fold less than the actual number of breeding adults (Heywood, 1986; Briscoe et al., 1992), populations must have about 1,000 individuals to maintain their genetic variation.[6]

7.3.1.1.6. *Habitat fragmentation.* A major area of uncertainty in conservation biology concerns the degree to which population subdivision influences the vulnerability of species to extinction. Even for fairly simple, single-factor investigations in which demographic or environmental sources of randomness are assumed to dominate (Quinn and Hastings, 1987, 1988; Gilpin, 1988), the debate about the effectiveness of a single large reserve as opposed to several small ones is far from being resolved. An advantage of a single large reserve is that it is buffered from demographic stochasticity, but multiple small reserves can buffer an entire species from extinction due to local catastrophes and environmental stochasticity. On the other hand, small isolated populations are precisely the ones that are expected to suffer from inbreeding depression, mutation load, and loss of adaptive potential. Much of the recent theoretical and empirical work on the dynamics of populations with a metapopulation structure can be found in recent volumes by Gilpin and Hanski (1991) and Burgman et al. (1992).

Population subdivision adds another dimension to species viability analysis, because questions are focused not just on the risk of extinction for an individual deme, but for an entire complex of demes. Levins (1970) called a collection of partially or totally isolated populations of the same species a metapopulation, and his early models for site occupancy form the conceptual basis of most current efforts in this area. Levins showed that in an ideal world consisting of an effectively infinite number of subpopulations, each with a constant probability of extinction E and a recolonization rate C, the entire metapopulation will eventually reach an equilibrium with a fraction $1 - E/C$ of the total sites occupied. Because of the randomness of extinction and colonization, the specific sites that are occupied will vary in time.

The intuitive notion behind Levins's work is that unless the extinction rate is zero, the total amount of suitable habitat for a species is unlikely ever to be completely occupied.

[6]The actual number depends in part on the biology of the organisms involved, such as sex ratio, breeding behavior, and so on. It can be greater than 1,000 if the effective population size is much smaller than the actual population size.

Elimination of suitable but unoccupied patches of habitat reduces the recolonization rate by making it more difficult for migrants to find suitable sites. Thus, habitat removal could theoretically have the paradoxical effect of increasing the fraction of apparently suitable habitat that is unoccupied, but this is due only to an overall decline in metapopulation size.

Lande (1987) introduced a series of habitat-occupancy models showing that if suitable patches are dispersed to a large enough degree that migrants are unlikely to find them, the local extinction rate will exceed the colonization rate. Thus, there exists a minimum fraction of the total landscape throughout a region that must be suitable for a species to persist. These extinction thresholds, defined by the demographic and dispersal properties of the species, demonstrate that locally abundant species can sometimes be very close to extinction if the proportion of suitable habitat is near the extinction threshold. This again emphasizes that population size alone is not always a good indicator of vulnerability to extinction.

Lande's (1987) models are idealized in that they envision a world consisting of two kinds of habitat patches—hospitable and inhospitable, all of equal size. The real world, of course, is more complex. Patches differ in size and shape, patch quality is usually a continuous variable, and some patches are connected by corridors, others not at all (see NRC, 1995a, chapter 5). More generalized approaches are discussed by Akçakaya and Ginzburg (1991). A significant feature of their approach is the inclusion of a correlation between the extinction probabilities of adjacent patches. This correlation, if positive, causes a reduction in the expected time to extinction. In other words, if all patches in an area became inhospitable at the same time, there would be no refuges available.

For many species, the adverse consequences of habitat fragmentation are not caused so much by a loss of total area as by changes in the quality of habitat due to the development of edge effects on the margins of reserves (Lovejoy et al., 1986). Edge effects range from microclimatic changes resulting from structural changes in the environment to major alterations in the vegetational community to invasions by exotic species from agricultural and urban settings. The complete impact of edge effects may require several years to develop and may ultimately extend for several kilometers beyond the edge of the reserve. Some attempts have been made to capture the key features of edge effects in mathematical models (Cantrell and Cosner, 1991, 1993). The issues are very complex because they involve interspecific interactions, such as competition between reserve and invading species. Ultimately, the practical application of any of these models requires a deep understanding of the ecology of the species under consideration.

7.3.1.1.7. *Supplementation.* An increasingly common strategy for maintaining wild populations of endangered species is augmentation with stock from breeding facilities, as in the case of hatcheries for Pacific salmonids. An implicit assumption of such procedures is that recipient populations, when they still exist, actually derive some benefit from an artificial boost in population size. There are, however, several reasons why long-term deleterious consequences of supplementation may outweigh the short-term advantage of increased population size.

First, over evolutionary time, successful populations are expected to become morphologically, physiologically, and behaviorally adapted to their local environments. Thus, the introduction of nonnative stock has the potential to disrupt adaptations that are specific to the local habitat. This type of problem takes on added significance when the population employed in stocking has been maintained in captivity. Captive environments are often radically different from those in the wild, and over a period of several generations, "domestication selection" can potentially lead to the evolution of rather different behavioral or morphological phenotypes (Doyle and Hunte, 1981; Frankham and Loebel, 1992; NRC, 1995b)—genotypes that perform well in the captive environment are expected to gradually displace those that do not. Furthermore, an overly protective captive breeding program may simply result in a relaxation of natural selection and the gradual accumulation of deleterious genes. For hatchery salmonids, egg-to-smolt survivorship is typically 50% or greater, as compared with 10% or less in natural populations (Waples, 1991; NRC, 1995b).

Second, local gene pools can be co-adapted intrinsically (Templeton, 1986). Just as the external environment molds the evolution of local adaptations by natural selection, the internal genetic environment of individuals is expected to lead to the evolution of local complexes of genes that interact in a mutually favorable manner. The particular gene combinations that evolve in any local population will be largely fortuitous, depending in the long run on the chance variants that mutation provides for natural selection. The breakup of co-adapted gene complexes by hybridization can lead to the production of individuals that have lower fitness than either parental type (outbreeding depression) and takes its extreme form in crosses between true biological species that cannot produce viable progeny. However, outbreeding depression can even occur between populations that appear to be adapted to identical extrinsic environments. The most dramatic evidence comes from reduced fitness in crosses of inbred lines of flies (Templeton et al., 1976) and plants (Parker, 1992), but crosses between outbreeding plants separated by several tens of meters can exhibit reduced fitness (Waser and Price, 1989), as can crosses between fish derived from different sites in the same drainage basin (Leberg, 1993). Outbreeding depression in response to stock transfer is a major concern in the management of Pacific salmon, which are subdivided into demes that are home to specific breeding grounds (Waples, 1991; Hard et al., 1992; NRC, 1995b).

Third, augmentation of wild populations with stock from captive breeding programs can have negative ecological or behavioral consequences. Unlike genetic effects, which can take several generations to emerge fully, ecological and behavioral effects can be immediate. For example, high-density hatchery populations of fish are prone to epidemics involving diseases that are uncommon in the natural environment. Such events provide strong selection for disease-resistant varieties of hatchery-reared fish, which subsequently can act as vectors to the wild population. The Norwegian Atlantic salmon is now threatened with extinction resulting from a parasite brought to Atlantic drainages by resistant stock from the Baltic (Johnsen and Jensen, 1986).

Fourth, if a wild population is small because of habitat loss or alteration, the increased population density that results from augmentation can increase competition for food, space, or whatever else the habitat provides. That competition can further reduce the size of the wild population. Harvest of augmented wild populations (particularly if harvest levels are based on total population) can reduce the wild segment of the population unless the harvest effort is directed away from the wild population. A captive breeding and reintroduction program is appropriate only when there is no alternative means of ensuring short-term population viability or when there is strong evidence of historical gene flow. Habitat loss and degradation are the main reasons species become threatened or endangered; therefore, the protection of habitat plays a greater role in preserving these species than captive breeding and reintroduction. For example, as of 1991, the species specialist groups of the International Union for the Conservation of Nature, which are international groups of scientists with expertise on specific kinds of animals, had completed conservation plans for 1,370 mammals. Of the recommendations in these plans, 517 concern protecting or managing habitat, while only 19 concern captive breeding and reintroduction (Stuart, 1991).

Captive breeding and reintroduction are appropriate when suitable unoccupied habitat exists and the factors leading to extirpation of the species from this habitat have been identified and reduced or eliminated. Under these circumstances, captive breeding and reintroduction of threatened and endangered species can be part of a comprehensive strategy that also addresses the problems affecting species in the wild (Foose, 1989; Povilitis, 1990; Ballou, 1992; NRC, 1992a). For example, captive breeding and reintroduction enabled the peregrine falcon (*Falco peregrinus*) to repopulate much of North America after the use of DDT was eliminated (Cade, 1990). Similarly, Arabian oryx (*Oryx leucoryx*) were successfully reintroduced in several areas of their original range where hunting was prohibited (Stanley-Price, 1989).

Captive breeding and reintroduction programs should be avoided when possible; however, once the need for such a program has been identified, it is advisable to initiate it as soon as possible. Starting the program before the wild population has been reduced to a mere handful of individuals increases a program's chances of success. Starting sooner provides time to solve husbandry problems, increases the likelihood that enough wild individuals can be captured to give the new captive population a secure genetic and demographic foundation, and minimizes adverse effects of removing individuals from the wild population.

Captive breeding and reintroduction programs are the most expensive forms of wildlife management (Conway, 1986; Kleiman, 1989) and involve research and management actions. Although genetic and demographic management techniques for captive populations are fairly well developed and can be applied to most species (Ballou, 1992; Ralls and Ballou, 1992), husbandry and reintroduction techniques tend to be species specific. Zoos do not know how to breed many species, such as cheetahs (*Actinomyx jubatus*), reliably in captivity. In such cases, expensive and time-consuming research on genetics, behavior, nutrition, disease, or reproduction might be necessary to find the reasons for lack of breeding success. The reintroduction of captive-bred individuals also poses substantial technical challenges. Considerable research, in captivity and in the field, often is necessary during the early stages of the reintroduction process to develop successful techniques (Kleiman, 1989; Stanley-Price, 1991).

7.3.1.2. *Focusing Conservation Efforts*

Life-history models can also help to identify the stages of an organism's life history most likely to be sensitive to conservation efforts. For example, NRC (1992b) concluded from life-history data and models that protecting juvenile and subadult sea turtles would have a greater effect on increasing population growth than reducing human-caused deaths of eggs and hatchlings. Similarly, by performing an analysis of the sensitivity of the population growth rate of the northern spotted owl to various demographic parameters, Lande (1988), based on the data available then, concluded that the most important contributors to the owl's survival were the adults' annual survival rate, followed by the survival rate of juveniles during their dispersal phase, and annual fecundity.

7.3.1.3. *Distribution of Extinction Times*

The preceding discussion summarizes the state of our knowledge of how various factors contribute to the risk of population extinction. For practical reasons, the existing theory focuses almost entirely on the expected time to extinction. However, in the listing and management of endangered species, the primary focus is usually on the likelihood of extinction within a given time frame (Shaffer, 1981, 1987; Mace and Lande, 1991). Risk analysis requires information on the dispersion of the probability distribution of extinction times about the mean. For the models previously cited and many others (Burgman et al., 1992), the distribution of extinction times typically is strongly skewed to the right, with the most likely extinction time (the mode) being substantially less than the mean. In general, it is probably more useful to estimate extinction probabilities as a function of time for different population sizes than to identify some specific MVP.

One conceptually simple way of relating risk to the mean extinction time is to assume that if the current ecological conditions remain stable, the probability of extinction per generation also remains stable.[7] That cannot be strictly true, even in a constant environment, because demographic and genetic sources of stochasticity will ensure that the probability of extinction is not constant in time. For example, if by chance the population size dwindles, the risk of extinction will be elevated above the average risk until the population has recovered to its average size.

7.3.2. Limitations of Our Ability To Estimate Risk

We close this section by again emphasizing that the practical utility of any extinction model depends on the validity of its underlying assumptions. Virtually all work on the vulnerability to extinction has taken a single-factor approach, under the assumption that this will at least yield an understanding of how the expected extinction time scales with population size when a single factor is operating. Other than analytical and computational simplicity, there seems to be little justification for this approach to population viability analysis. Chapter 5 in the 1995 NRC report (NRC, 1995a) gives some examples of population viability analyses that have been useful and points out the need to recognize the uncertainties discussed here. In nature, populations are exposed to multiple sources of risk simultaneously. Synergism between different risk factors is not reflected in many models, and therefore the risk of extinction can be underestimated (see Gabriel and Bürger, 1992). A field example of such synergism was described by Woolfenden and Fitzpatrick (1991); epizootic infections of the Florida scrub jay, which reduced local populations by 50%, also lowered reproductive success in the following seasons even after the death rates had returned to normal.

Although analytical results are valuable as guides to research and as methods of comparing the effects of various environmental and management scenarios, they are probabilistic in nature, so

[7] In this case, the conditional probability of extinction in any generation (given that the population has survived to that point) is simply the reciprocal of the mean extinction time, i.e., $p_e = 1/_e$, where $_e$ is the mean time to extinction measured in generations. Because the probability that extinction does not occur in (x - 1) consecutive generations is $(1 - p_e)^{x-1}$, and the probability that those (x - 1) generations are immediately followed by extinction is p_e, the probability of extinction in generation x is $p_e(1 - p_e)^{x-1}$. With this approach, the cumulative probability that the population will be extinct by generation t can be computed by solving the preceding expression for $x = 1$ to $x = t$, and summing these probabilities. Results in Gabriel and Bürger (1992) and Tier and Hanson (1981) suggest that this approach might provide a good first-order approximation to the distribution of extinction times due to demographic and environmental stochasticity under a broad range of conditions.

they often ignore the underlying mechanisms. Perhaps their greatest potential is in combination with empirical evidence on extinction times, both in the laboratory and in the field (see for example Pimm et al., 1993). It remains to be seen how relevant such results are to natural populations. Most of the work on vulnerability of species has also focused on nonfragmented populations and, except in the case of asexual populations (Lynch et al., 1993), few formal attempts have been made to incorporate genetics into extinction models. There is a clear need for models that predict distributions of extinction times as a function of population density, demographic rates, mating system, environmental variation, etc. These models, which can only be evaluated by computer simulation (Shaffer and Samson, 1985; Caswell, 1989; Menges, 1992), can be expected to advance substantially in the next few years because computational power is now widely available.

7.4. CONCLUSIONS AND RECOMMENDATIONS

Since the implementation of the ESA, numerous models have been developed for estimating the risk of extinction for small populations. Although most of these models have shortcomings, they do provide valuable insights into the potential impacts of various management (or other) activities and of recovery plans. With only a few exceptions, biologically explicit quantitative models for risk assessment have played only a minor role in decisions associated with the ESA. They should play a more central role, especially as guides to research and as tools for comparing the probable effects of various environmental and management scenarios.

Despite the major advances that have been made in models for predicting mean extinction times, the existing treatments still have substantial limitations. Most of the models are unifactorial in nature and fail to incorporate the negative synergistic effects that multiple risk factors have on the time to extinction. Efforts to jointly integrate genetic, demographic, and environmental stochasticity into spatially explicit frameworks are badly needed.

Most extinction models primarily address the mean extinction time. Because decisions associated with endangered species usually are couched in fairly short time frames—less than 100 years—models that predict the cumulative probability of extinction through various time horizons would have greater practical utility.

Results from population-genetic theory provide the basis for one fairly rigorous conclusion. Small population sizes usually lead to the loss of genetic variation, especially if the populations remain small for long periods. If the members of the population do not mate with each other at random (the case for most natural populations), then the effect of small size on loss of genetic variation is made more severe; the population is said to have a smaller *effective size* than its true size. Populations with long-term mean sizes greater than approximately 1,000 breeding adults can be viewed as genetically secure; any further increase in size would be unlikely to increase the amount of adaptive variation in a population. If the effective population size is substantially smaller than actual population size, this conclusion can translate into a goal for many species for survival of maintaining populations with more than 1,000 mature individuals per generation, perhaps several thousand in some cases. An appropriate specific estimate of the number of individuals needed for long-term survival of any particular population must be based on knowledge of the biology of the organisms involved, such as sex ratios and breeding behavior. If information on the breeding structure of that species is lacking, information about a related species might be useful.

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RELATED SCIENTIFIC ASSESSMENTS

8. ECOLOGICAL ASSESSMENTS IN ECOSYSTEM MANAGEMENT

8.1. SUMMARY

The case studies discussed in this chapter were assessments developed to meet the needs of decision makers responsible for managing ecosystems. All of the case studies are based on an underlying concept of assessing risk. The specific studies reported range from approaches that directly derive from ecological risk assessment, as discussed in Chapter 1 of this document, to approaches that parallel many of the ecological risk assessment concepts but have no derivative linkage to ecological risk assessment. For that latter group of case studies, the assessments tended to be custom designed to address the specific of concerns of the involved managers.

Comparison of the case studies with the ecological risk assessment framework presented in Figure 1-1 indicates general alignment with the conceptual blocks of the framework, but considerably less alignment with the specific ecological risk assessment exposure to risk paradigm. All of the case study assessments involved dialogues between assessors, managers, and interested parties in the planning phase. They all involved problem formulation, but most frequently that formulation was based on providing comprehensive assessments of ecosystem processes, status, and trends. Analyses followed from the problem formulations and lead to characterization of the ecosystems involved. The results were communicated to the ecosystem managers and other interested parties, usually in the form of options for managing for a range of future ecosystem outcomes. Risk was at least implicit in assessing these outcomes, and in several of the cases it was explicitly considered. For a schematic comparison of ecological risk assessment with the ecosystem management model, Figure 1-1 may be compared with Figure 8-1. The second block in Figure 8-1 (entitled “Assessments”) maps closely with the conceptual basis of ecological risk assessment.

Three sets of case studies are discussed in this chapter. The Interior Columbia River Basin Scientific Assessment was a multiagency activity aimed at providing an integrated assessment as a basis for evaluating environmental impact statement (EIS) alternatives for the ecosystems in an area that included the Columbia River Basin within the United States and east of the Cascade crest and portions of the Klamath and Great Basins in Oregon. The Southern Appalachian Assessment provided an ecological description of conditions within a region encompassing parts of seven States, extending from the Potomac River to northern Georgia and the northeastern corner of Alabama. The EPA Watershed Assessments evaluated the feasibility of applying the ecological risk assessment process as provided by the Framework for Ecological Risk Assessment (U.S. EPA, 1992) to the more complex context of watershed ecosystem management. Five watersheds were included: Big Darby Creek in central Ohio, Clinch River Valley in southwest Virginia, Middle Platte River in south central Nebraska, Middle Snake River in south central

Idaho, and Waquoit Bay on the southern shore of Cape Cod. Each of these assessments involved an integrated ecosystem approach to making land management decisions.

The role of science in these assessment activities, as in risk management, is to provide objective information for decision making. That information is framed in a manner that meets the needs of decision makers, while strictly maintaining scientific objectivity, integrity, and quality control. Decision maker needs are agreed upon in an interactive process between decision makers and assessment managers. Although new research is seldom performed within the assessment activity, synthesis of existing information often provides new knowledge or perspectives about the ecosystems being assessed. In all of the case studies reported in this chapter, science played a critical role in facilitating definition of the pertinent management questions to be addressed, establishing information on which to build the assessments, maintaining quality control and assurances protocols, analyzing and synthesizing information, and working to communicate results to responsible managers and interested parties.

> Christensen et al. (1996) defines ecosystem management as "...management driven by explicit goals, executed by policies, protocols, and practices, and made adaptable by monitoring and research based on our best understanding of ecological interactions and processes necessary to sustain ecosystem composition, structure and function."

8.2. INTRODUCTION

Ecological risk assessment is a process of organizing and analyzing data, information, assumptions, and uncertainties to evaluate the likelihood of adverse ecological effects (U.S. EPA, 1996). Ecosystem management is a process for maintaining the integrity of ecosystems over time and space (Quigley et al., 1996a). Ecosystem sustainability increasingly is being stated as the goal of ecosystem management. A variety of ecosystem assessments have been led by Federal agencies in recent years. These assessments were intended to help decision makers and other interested parties better understand and evaluate consequences of potential regulatory or natural resource allocation actions within a larger social, economic, and ecological framework. This chapter provides information on the ongoing development of the ecological risk assessment process and the ecosystem management assessment process. The linking of these two processes can bring improved organizational and analytical consistency to the assessment of information in support of multiple scales of resource planning and decision making needed for ecosystem management. The intent of this chapter is to promote dialogue between the two communities and enhance cross-community appreciation of needs and approaches.

Section 8.2 of the chapter presents an overview of several ecosystem assessments done in recent years. Section 8.3 provides several Agency case study illustrations of assessment approaches. Section 8.4 discusses risk assessment methodology development. Section 8.5

examines ecological risk assessment in the ecosystem decision-making context. Section 8.6 discusses possible next steps, beginning with a description of cost-benefit considerations followed by suggestions for expanded use of the proposed EPA ecological risk assessment guidelines in ecosystem assessments; the section concludes with an analysis of technical and research challenges.

A fundamental challenge to ecosystem management is the need to understand and manage complex ecosystems simultaneously across large and small temporal and spatial scales (Quigley et al., 1996a). In light of this challenge, decision makers are faced with making complex social, economic, and environmental decisions. These decisions bring with them an inherent level of uncertainty for decision makers and stakeholders alike. Decision makers and stakeholders need to recognize this inherent uncertainty and be flexible enough to adjust their decisions in the face of surprise. A general planning model for ecosystem management was put forward by Quigley et al (1996a) (Figure 8-1). The process has four basic parts: monitoring, assessments, decision, and implementation.

Ecological risk assessments are tools decision makers can use to help identify and, it is hoped, reduce uncertainty throughout the decision-making process. Ecosystem assessments are also tools to help decision-makers. Ecosystem assessments follow general concepts as shown in Figure 8-1, but they do not have an existing set of definitional rules. The general concepts include acknowledgment of stakeholders and their questions, development of situational analyses, identification of trade-offs and limits, development of an understanding of future conditions, and assessment of risk for issues of concern. The primary reason for conducting ecosystem assessments then is to provide a framework for decision makers and stakeholders to help them understand and evaluate the consequences of actions with respect to regulation and/or allocation of natural resources within the larger social, economic, and ecological context. The ecosystem management process presented in Figure 8-1 outlines several sections where ecological risk assessment can link with ecosystem management. In the assessments section of the process, assessing risks for issues of concern is presented. In ecological risk assessment, risk characterization involves addressing the likelihood and consequences, weight of evidence, uncertainty, and other factors. For determining the impact of a stressor, multiple stressors, or a management scenario, a qualitative or quantitative analysis of the likelihood and consequences of the scenario would be valuable for the decision makers. Supporting the “how sure are we of this”

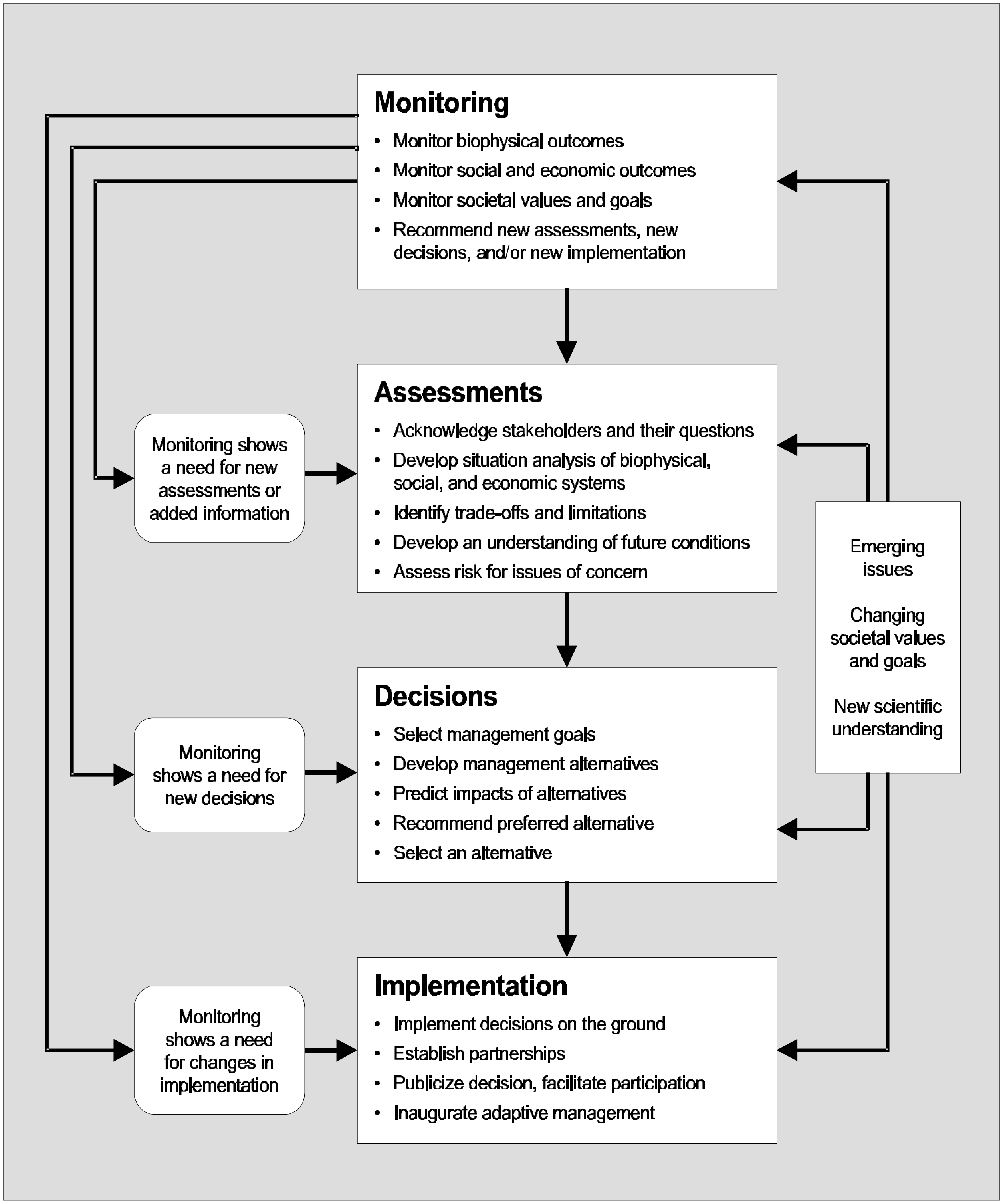

Figure 8-1. Ecosystem management model. Each step has several parts. Because the model is iterative, external or internal influences can initiate any step in the process, and the process never ends.

Source: Quigley et al., 1996a.

question, uncertainty and lines-of-evidence analyses provide additional information to the managers. In the decisions section of the ecosystem management process, the prediction of impacts from alternatives is presented. Prediction of the likelihood and consequences of a management action on an ecological system can utilize ecological risk assessment methods. Chapter 4 presents an effective process for nonindigenous species that could be adapted for multiple stressors or management alternatives.

It is within this context of ecosystem management, uncertainty, and adaptation that a series of "lessons learned" workshops, designed as an adaptive learning approach to ecoregional assessments, are being conducted to discuss and document the knowledge gained by various assessment teams throughout the country.

The first iteration of ecosystem assessments, which include the Report of the Forest Ecosystem Management Assessment Team, the Columbia River Basin Assessment, and the Sierra Nevada Ecosystem Project, were mandated by the President. These were generally high-cost projects ($6 million to $36 million) directed at a number of high-profile issues in the Pacific Northwest and Northern California.

Second-generation ecosystem assessments were chartered by decision makers (Forest Service Regional Foresters) for the purpose of providing state-of-the-art information needed to revise forest land management plans. These are best represented by the recently completed Southern Appalachian Assessment, the ongoing Great Lakes Assessment, the Northern Great Plains Assessment, and the Ozark/Ouachita Highlands Assessment. These are low-cost alternatives ($0.5 million to $2 million) to the earlier generation noted above.

Key findings from the "lessons learned" workshops are summarized below (USDA, 1996).

- The assessment process

  —Assessments are not decision-making documents. However, they do provide a synthesis of information in support of multiple scales of resource planning and decision making.

  —Assessments should be issue driven.

  —Data synthesis and acquisition need to be strongly focused on the assessment issues.

  —Preassessment planning is critical to conducting an assessment.

  —Process, structure, and function are the ecosystem components evaluated during the assessment process. These components need to be analyzed at multiple spatial and temporal scales.

  —Broad-scale assessments are a rich source of new information. Recognizing emergent properties of ecosystems at broader scales is an important part of this new information.

- Linkages to other assessments and programs

  —There is a need to develop implementation, effectiveness, and validation monitoring programs at multiple scales. These programs should update assessment information over time.

  —Ecoregional assessments can be linked using common information themes and protocols.

  —Cooperation with the Federal Geographic Data Committee will help ensure data linkages among other national, regional, and landscape assessments.

- Public involvement and partnerships

  —Public participation for ecoregional assessments should be based on adaptive management principles focused on achieving awareness and active involvement of a diverse array of stakeholders.

  —Public involvement is crucial to the success of assessments and provides benefits in later decision-making forums.

  —Because of their sheer size and the complexity of ownership patterns, ecoregional assessments have a greater need for partnerships than any other planning process.

- Assessment products

  —Assessments produce various tangible and intangible products, including findings, data, maps, references, changed relationships with participating agencies and the public, and institutional and organizational change. Products that address immediate needs and issues are most likely to get immediate use.

- Information management

  —An interagency commitment needs to be made to ensure maintenance of data, maps, meta data, etc., for future assessment and monitoring efforts.

  —Establishing an information management infrastructure before the assessment should be a high priority.

8.3. CASE STUDIES AND EXAMPLES

8.3.1. Interior Columbia River Basin Scientific Assessment[8]

The Interior Columbia River Basin Ecosystem Management Project was initiated by the Forest Service (FS) of the U.S. Department of Agriculture and the Bureau of Land Management (BLM) of the U.S. Department of the Interior in response to decisions to adopt an ecosystem-based management strategy; the need to replace interim direction; concerns about declining forest, rangeland, and aquatic health; and concerns about single-species approaches to conservation and management. The project area includes those portions of the Columbia River Basin within the United States and east of the Cascade crest and portions of the Klamath and Great Basins in Oregon (the Basin). The primary products called for in the charter include (1) a framework for ecosystem management (Haynes et al., 1996), (2) an integrated scientific assessment (Quigley et al., 1996a; Quigley and Arbelbide, 1996), (3) two environmental impact statements (EISs) addressing management of FS- and BLM-administered lands within the Basin, and (4) an evaluation of the EIS alternatives (Quigley et al., 1996b). The framework, assessment, and evaluation of alternatives are products of the science team, and the EISs are products of the EIS teams. In addition to these primary products, more than 40 scientific publications are expected from this work over the next several years. The following material is drawn mostly from the executive summaries of the science documents cited above. The Basin includes 145 million acres, with the FS and BLM administering more than one-half (76 million acres) of the area. This sparsely populated area covers portions of 7 States and 100 counties. It encompasses a variety of climatic, topographic, socioeconomic, forest, and rangeland conditions. It extends from the Continental Divide on the east to the Cascade crest on the west. It includes resources of international significance such as Yellowstone National Park and Hells Canyon. It is home to some 22 Native American Indian tribes and more than 3 million people.

8.3.1.1. *Framework*

With the announcement by the FS and BLM of the intent to adopt an ecosystem-based strategy came the need to frame the interactions among decisions at multiple levels and their relationship with assessments. The framework assumes that the purpose of ecosystem management is to maintain the integrity of ecosystems over time and space. It is based on four ecosystem principles: ecosystems are dynamic, can be viewed as hierarchies with temporal and spatial dimensions, have limits, and are relatively unpredictable. This approach recognizes that people are part of ecosystems and that stewardship must be able to resolve tough challenges,

[8]This section provides examples of a range of assessments prepared by a number of agencies. The views expressed represent those of the authors of each assessment summary.

including how to meet multiple demands with finite resources. The framework describes a general planning model for ecosystem management (Figure 8-1) that has four iterative steps: monitoring, assessment, decision making, and implementation. Since ecosystems cross jurisdictional lines, the implementation of the framework depends on partnerships among land managers, the scientific community, and stakeholders. It proposes that decision making be based on information provided by the best available science and the most appropriate technologies for land management.

8.3.1.2. *Integrated Scientific Assessment*

This integrative assessment links landscape, aquatic, terrestrial, social, and economic characterizations to describe biophysical and social systems. Integration was achieved through the use of a framework built around six goals for ecosystem management and three different views of the future. The assessment represents the largest and most comprehensive assessment of ecosystems undertaken. The overall purpose of the assessment is to develop a better understanding of the current, historical, and potential future biophysical, economic, and social conditions and trends in the Basin. The assessment is not a decision document nor does it resolve specific resource issues. Rather, the assessment provides the foundation for proposed additions or changes to existing FS and BLM resource management plans to consistently manage risks and opportunities at multiple scales. Some highlights of the findings include the following:

- There has been a 27% decline in multilayer and a 60% decline in single-layer old-forest structures from historical levels, predominantly in ponderosa pine and Douglas-fir forest types.

- Aquatic biodiversity has declined through local extirpations, extinctions, and introduction of exotic fish species, and the threat to riparian plants and animals has increased.

- Some watershed disturbances, both natural and human induced, have caused and continue to cause risks to ecological integrity, especially owing to isolation and fragmentation of fish habitat.

- The threat of severe lethal fires has increased by nearly 20%, predominantly in the dry and moist forest types.

- Rangeland health and diversity have declined because of exotic species introductions, historical grazing, changing fire regimes, agricultural conversions of native shrublands and herblands, and woodland expansion in areas that were once native shrublands and herblands.
- Human communities and economies of the Basin have changed and continue to change rapidly, although rates of change are not uniform.

There are tremendous opportunities to restore ecosystem processes and functions as well as provide for the flow of goods and services demanded by society. In addition to tremendous opportunities, risks are also associated with attaining these opportunities. Some risks are related to natural events such as wildfire, insect, and disease outbreaks, while other risks are associated with management activities such as road building, timber harvest, and prescribed fire. These risks and opportunities vary greatly across the Basin. The assessment has characterized the broad-level risks and opportunities across the Basin. Realizing the opportunities and managing the risks involves working within the adaptive management framework presented.

8.3.1.3. *Ecosystem Integrity*

Drawing from the detailed assessment of historical and current conditions within the Basin, two concepts were used to integrate the major functional areas to determine status of the ecosystems. Maintaining the integrity of ecosystems is assumed to be the overriding goal of ecosystem management. The integrity of ecosystems encompasses both social and biophysical components; the health of the Basin's people and economy is not a separate issue from the health and integrity of other ecosystem components. Ecological integrity refers to the presence and functioning of ecological components and processes. The basic components of ecological integrity include the forest, range, and aquatic systems, with a hydrologic system that overlays the landscape as a whole. The counterpart to ecological integrity is socioeconomic resiliency (measured at the county level), which in the context of ecosystem management reflects the interests of people to maintain well-being through personal and community transitions.

8.3.1.4. *Composite Ecological Integrity*

Integrity ratings were developed for five ecological components: forestland, rangeland, forest and rangeland hydrologic, and aquatic systems. This information became the primary basis for estimating composite ecological integrity for each subbasin (approximately 850,000 acres in size) within the Basin. Currently, 16% of the Basin is rated as having high relative composite ecological integrity, 24% as moderate, and 60% as low. Eighty-four percent of the systems with high integrity are on FS- and BLM-administered lands, while 39% of the low-integrity systems are on FS- and BLM-administered lands.

8.3.1.5. *Socioeconomic Resiliency*

Socioeconomic resiliency, estimated at the county level for this analysis, dealt with the adaptability of human systems. High ratings imply that these systems are highly adaptable; changes in one aspect are quickly offset by self-correcting changes in other sectors or aspects.

High levels of socioeconomic resiliency should reflect communities and economies that are adaptable to change, where sense of place is recognized in management actions, and where the mix of goods, functions, and services that society wants from ecosystems is maintained. A low rating applies to 54 Basin counties. Another 20 Basin counties were rated as having an intermediate level of resiliency. A high socioeconomic resiliency rating applies to the 26 Basin counties that are more densely populated. While 68% of the area within the Basin is rated as having low socioeconomic resiliency, 67% of the people of the Basin live in areas with high socioeconomic resiliency.

8.3.1.6. *Findings From the Future Management Options*

The current draft EIS has primarily considered three options: (1) continuation of current approaches, (2) restoration emphasis, and (3) reserve area emphasis. Evaluations of the options benefitted from the underlying science documents and assessments conducted in the basin. The public comment period on the draft EIS has closed. Land managers and stakeholders will now engage in a dialog about the content and process of selection of the preferred strategy for managing the FS- and BLM-administered lands.

8.3.2. The Southern Appalachian Assessment

The Southern Appalachian Assessment (SAA) is an ecological description of conditions within a region encompassing parts of seven States. The area extends southward from the Potomac River to northern Georgia and the northeastern corner of Alabama. The SAA assembles the best available knowledge about the land, air, water, and people of the region. The SAA does not specifically apply typical risk assessment tools. It does attempt to describe change in the environment and the stresses that affect it. It is similar to risk assessment in that it avoids recommending actions.

The recently completed assessment was not the first. Early in the 20th century, the Appalachian landscape and its natural resources had been badly abused by destructive agricultural practices and exploitive logging. In 1901, at the request of the U.S. Congress, the Department of Agriculture conducted a similar assessment for the region. Its findings led to the Weeks Act, which authorized the establishment of national forests and national parks in the eastern United States.

Although there was no specific statutory requirement for the latest assessment, national forest management plans required by the 1976 National Forest Management Act had been in place for more than 10 years and needed to be revised. The management of national forests and other Federal lands is directly influenced by the biological, social, and economic conditions that surround them. Also, Federal and State regulatory agencies were concerned that increasing population pressures and economic development were adversely affecting environmental quality in the region. Thus, there was a need for a comprehensive and credible source of information to serve as a basis for planning.

Even before the SAA got under way, Federal and State agencies in the Southern Appalachian region had worked together on several projects of mutual interest. A coordinating group had been established, initially to address land management problems, but later expanded to include most environmental issues within the area. This was the Southern Appalachian Man and Biosphere (SAMAB) program. SAMAB now includes 12 Federal and 3 State agencies. Through the coordination of the SAMAB program, most of these agencies were involved in some way in conducting the SAA.

The SAA began in the spring of 1994. A dialog that involved SAMAB agencies and forest planners outlined a number of issues that needed to be addressed. There was no single issue producing conflict or confrontation, but there was widespread concern for the health and welfare of the region's resources. Starting with an initial set of issues, a series of public meetings was held at different locations within the area. People were told about the assessment that was planned and asked about their concerns and suggestions. The issues and concerns became the basis for a set of questions that the assessment would address.

The SAA was organized around four major environmental components: air, land, water, and people. Interagency teams were established to address each of these themes. An initial evaluation of the data indicated the need for a strong emphasis on map-based geographic information system technology. An interagency policy group was formed to guide the assessment. One of the group's first functions was to establish constraints or targets for the time of completion, money and people available, size of reports, and sources of data. Early in the process, it was decided to invite the public to attend and participate in most aspects of the assessment.

Each of the four major topics making up the assessment culminated in separate technical reports (atmospheric, aquatic, terrestrial, and social/cultural/economic reports). Although the analyses differ, the reports have several common features. Each starts with a set of questions that were derived from the issue identification process. The questions served to guide the analysis and to define the scope of the assessment. In addition, each interagency team was asked to describe the current resource situation and, to the extent possible, look for past and future trends in resource condition. Part of the assessment also consisted of evaluating the quality of available data sources and documenting future research and monitoring needs. The following paragraphs give a brief summary of each assessment topic.

The atmospheric team concentrated its analysis on nitrogen oxide, sulfur dioxide, particulate matter, and volatile organic compounds. These pollutants are important because the secondary pollutants formed from them are suspected of reducing visibility, producing ozone, and having consequent impacts on vegetation and human health; the pollutants also are important because of the acid deposition impacts on terrestrial and aquatic environments. In addition, these are the pollutants directly affected by the Clean Air Act legislation. The report describes the location of emissions and concentrations where emissions are greatest, and it projects likely future trends. Visibility is especially important in the SAA analysis because the Clean Air Act established as a national goal the "prevention of any future, and the remedying of any existing, impairment of visibility in mandatory Class 1 Federal areas where impairment results from man-made pollution." The majority of the visibility data was obtained in the seven Class 1 areas within the SAA region.

The terrestrial report is divided into two separate sections: (1) plant and animal resources and (2) forest health. The report responds to the considerable interest in the status of threatened, endangered, or sensitive species. Of more than 25,000 species known to inhabit the area, 472 were given special attention. The group includes 51 species that are federally listed as threatened or endangered and 366 whose numbers are sufficiently restricted that their populations are considered at risk. Most of these species can be grouped into 19 associations based on similar habitat requirements. Historically, the most significant event to affect the region's forests was the initial logging that was largely accomplished in the early decades of this century. Perhaps equally profound, although less dramatic, are the effects of a number of forest health factors. The chestnut blight, gypsy moth, and dogwood anthracnose have altered species composition of the region's forests. Other recently discovered diseases such as hemlock woolly adelgid and butternut canker are also cause for concern. Although historic data are inconclusive, it seems clear that the most serious threats to the health of the region's forests are coming from exotic pests introduced from other parts of the world.

The headwaters of nine major rivers lie within the boundaries of the Southern Appalachians, making it the source of drinking water for most of the Southeast. The aquatic assessment compiled the best available data on water resource status and trends, riparian condition, impacts of various land management or other human activities, water laws, aquatic resource improvement programs, and water uses. The report discusses the distribution of aquatic species and identifies some problems, including degraded streams, eutrophication of lakes, and the impacts of increasing human population and development. There is general agreement, however, that water quality has improved significantly since the adoption of the Clean Water Act in 1972.

Humans are a part of the ecosystem. Natural resource values are derived from the utility and aesthetic or intrinsic benefits that come from human culture. The social/cultural/economic assessment looked at four aspects of human influence: (1) communities and human influences, (2) the timber economy, (3) outdoor recreation, and (4) roadless and designated wilderness areas.

The relationship between people and public lands in the Southern Appalachians has changed greatly during the past two decades. The growing economy has become more diverse and less dependent on manufacturing. Newcomers to the region, many of them retirees, resort owners, or those employed in service industries, are more interested in scenery and recreation than in resource extraction. Also, the increasing population throughout the area is fragmenting land use and ownership, with adverse effects on wildlife habitat and timber availability. These changes are reflected in diverse, and often incompatible, demands on public lands. The assessment was aimed at better understanding the public and how their collective values have changed in recent years. This should be useful to both land managers and community planners.

The SAA documents consist of four technical reports and a summary report. But equally important are two other products of the assessment. The first is a set of five computer disks (CD-ROMs) that contain all the maps and data used in the assessment in digital form. These were distributed to the 400 selected Federal Depository Libraries used by the U.S. Government Printing Office and to individuals who requested them. The second medium is the Internet. In-depth versions of the text and data are available on the SAMAB, Forest Service, and Info South home pages on the World Wide Web (WWW).

The spirit of the SAA can best be summarized by a quotation from the documents: “The Southern Appalachian Assessment was accomplished through the cooperation of federal and state natural resource agency specialists. The strong emphasis placed on working together toward a common goal is increasingly recognized as essential to effective government operation. Teamwork has strengthened our understanding and communication. With the assessment as a framework for future action, government policy and management can become more consistent and better coordinated.” This basic principle is being applied as various groups work to further apply the information contained in the SAA.

8.3.3. EPA Watershed Assessments

EPA, other Federal and State agencies, environmental groups, and communities are placing increasing emphasis on community-based environmental protection and integrated ecosystem management. This emphasis arises from a recognition that the impacts of multiple human activities combine in the environment to cause significant adverse ecological effects that are not amenable to regulation under current environmental law. Unless these stressors are managed at the community level, local and national environmental goals may not be achievable. As the Agency shifts emphasis from command and control toward voluntary compliance and community-based environmental protection, it becomes critical that EPA provide the scientific basis for community-level management decisions. States and local organizations need a process and tools they are able and willing to use for determining what ecological resources are at risk and how best to protect those resources through management action. Case studies for evaluating risk to watershed ecosystems were initiated to develop examples and guidance on how to use science more effectively in ecosystem management.

8.3.3.1. *Background*

The watershed ecological risk assessment case studies were initiated in September 1993 to evaluate the feasibility of applying the ecological risk assessment process as provided in the Framework for Ecological Risk Assessment (U.S. EPA, 1992) to the more complex context of watershed ecosystem management. The Risk Assessment Forum and the Office of Water agreed to jointly sponsor the development of prototype ecological risk assessment case studies in watersheds under the guidance of a Risk Assessment Forum technical panel. The case study watersheds served as natural laboratories where teams used the process of ecological risk assessment to address ecosystem-level problems concerning diverse stressors, ecological values, and political and socioeconomic concerns in watersheds of different type, size, and complexity. The case studies served as a mechanism for learning about key management and research questions, limitations to the risk assessment process provided in the framework report, and issues surrounding involvement by interested parties that must participate in resource management.

Watershed ecosystems were chosen as the landscape unit for ecological, pragmatic, and programmatic reasons: (1) Watersheds are natural geomorphological units with definable boundaries where water flows across the landscape and collects in surface water bodies and groundwater. Because water flows across a landscape, the effect of human impacts occurring on land and directly in the water become combined as water flows toward collection basins such as rivers, lakes, wetlands, and estuaries, thus providing an effective landscape unit to assess the combined and cumulative effect of multiple stressors. (2) Watershed ecosystems are highly flexible in size. The size defined is based on the type of issues and relevant management decisions. A small community may be interested in the watershed in its valley and may focus management efforts at its level of influence, even though its watershed is part of a larger system. A State may choose to focus on a watershed that covers one-quarter of the State in order to organize permitting activities. Multiple States may become involved in cooperative management of large watersheds that cross political boundaries. Thus, watersheds can be local or regional in scope, and can cover multiple ecologically diverse regions. (3) Clean abundant water will increasingly become a highly valued limiting resource, both for direct human use and for supporting ecosystems. (4) EPA is encouraging States to organize regulatory and nonregulatory efforts according to watershed boundaries. This is intended to focus efforts in such a way as to promote the coordination of management efforts to improve environmental protection and reduce management cost. Geographic areas defined by a watershed are not appropriate for all environmental problems requiring management. The type of assessment question being asked determines the rationale for defining landscape boundaries. For example, a watershed would be appropriate for addressing risk to aquatic resources within a surface water body but would not be effective for concerns about air pollution in a forest ecosystem that covers parts of several watersheds. Although the case studies are focused on watershed ecosystems, the project's focus is on the process of conducting risk assessments for ecosystem-level problems. This process is readily adaptable to other ecosystem management problems.

8.3.3.2. *Process*

The case studies were initiated in 1993 through joint sponsorship by the Office of Water and the Office of Research and Development and administered under the Risk Assessment Forum through a technical panel.

8.3.3.3. *Watershed Case Study Selection*

Early in 1993, a solicitation for candidate watersheds for the project was announced and resulted in more than 50 applications. Watersheds were selected for the project on the basis of specific selection criteria, including data availability, identification of local participants, diversity of stressors, and significant and unique ecological values. The watersheds selected represent different surface water types; an array of chemical, physical, and biological stressors; and a diversity of valued ecological resources, scales, management problems, socioeconomic circumstances, and regions. Case study teams were established and began work in September 1993.

8.3.3.4. *Case Study Teams*

Each case study is being developed by an interdisciplinary, interagency team of scientists and natural resource managers. Professionals recruited for the teams include EPA scientists and managers from regions and program offices, State scientists and regulators, and scientists from other Federal agencies, nongovernmental groups, industry, and academia. When forming teams, every effort was made to recruit individuals with expertise in ecological risk assessment, ecological processes, the ecological resources and stressors in the targeted watershed, and ecosystem management. Recruitment has been a continuing process throughout development. Team size ranges from 10 to 50 members and participants, and other professionals are consulted as needed. The teams hold regular meetings (normally by conference call), and all teams have met in the watershed as part of the work on the case study.

8.3.3.5. *Characteristics of Selected Watersheds*

Five watersheds were selected for the project: Big Darby Creek in central Ohio, Clinch River Valley in southwest Virginia, Middle Platte River in south central Nebraska, Middle Snake River in south central Idaho, and Waquoit Bay on the southern shore of Cape Cod in Massachusetts. These watersheds are diverse in size, type, ecological characteristics, stressors, and socioeconomic context. Although ground water is an important element in several of the case studies and is addressed in the assessments, the watershed boundaries were defined by surface water flow. Only the Big Darby Creek and Waquoit Bay case studies include the hydrologic boundaries of an entire watershed. The Clinch River Valley includes most of the watershed as defined by topography, but the southern part of the watershed was inundated because of dam construction and the reservoir is excluded. Both the Middle Snake River and Middle Platte River watershed case studies are based on important middle segments of the rivers but do not attempt to consider the very large watershed system of which they are a part.

Big Darby Creek is a medium-sized river system in a relatively flat agricultural landscape that is considered to be of high quality. One of the Nature Conservancy's Last Great Places, it contains highly diverse communities of fish and mussels, good riparian areas, and clean water. Agricultural management practices and urban and suburban encroachment are placing these values at risk. The local community is interested in better land use planning and management practices to prevent degradation.

The Clinch River Valley contains highly valued fish and mussel communities and includes the greatest diversity of mussels in North America, many of which are rare and endangered. The valley is also a Last Great Place, but agricultural practices and mining are major stressors in the high-relief terrain environment. Protection of these valued resources must be done in a socioeconomically depressed area.

The Middle Platte River wetlands support millions of birds migrating in the Central Flyway, including the endangered whooping crane, as well as many resident species. Competition for water in the Middle Platte River, part of our Nation's breadbasket, is a politically charged issue. Hydrological modifications have changed the broad-braided river wetlands of the Middle Platte to a 50-mile stretch of narrowed wetland systems.

The Middle Snake River, once charged by natural springs bursting from canyon walls, is now primarily fed by irrigation return flows. Considered the most impaired watershed among the case studies, the Snake River has become an algae- and sediment-choked stream in many parts of its reach. Better management of dams, irrigation return flows, sediments, and trout hatcheries is central for protecting and restoring at least part of the river's function.

Waquoit Bay is the smallest watershed among the case studies, valued for its aesthetic beauty, recreational opportunities, and commercial fisheries. Currently, residential development, a

Superfund site, and other activities in the watershed are placing these values at risk. The fairly affluent community is seeking ways to reverse degradation and regain ecological values.

8.3.3.6. *Resources to Support Case Study Development*

The case studies were designed to demonstrate what can be accomplished using available data and limited resources. The project was organized to approximate the kinds of expertise, resources, and data likely to exist in communities that would be responsible for using guidance for implementing ecosystem management at the community level. The following statements characterize case study resources:

- Members and participants on watershed teams are professionals from diverse disciplines whose time was volunteered by their organizations for the effort.
- A small minority of participants were familiar with risk assessment.
- Each watershed ecosystem is being evaluated within the context of many competing socioeconomic and political concerns.
- The case studies are being conducted with minimal funding and a reliance on existing data.

8.3.3.7. *Lessons Learned*

The watershed ecological risk assessment case studies were developed using available guidance on ecological risk assessment as presented in the framework report (U.S. EPA, 1992). During case study development, several adjustments to this process were found to be valuable. Each team's experiences added dimension to our interpretation about what adjustments were needed. Sometimes teams experienced successes, sometimes readjustments and redirection. All were important learning opportunities.

We believe that the process that emerged from the case studies is sound and valuable and will be the focus of detailed guidance in the future. However, all of the lessons learned are now incorporated at a general level in the Agency's Draft Proposed Guidelines for Ecological Risk Assessment (U.S. EPA, 1996). Specific issues and changes that emerged from conducting the case studies include how value-initiated risk assessments alter the process of problem formulation, the importance and process of "planning" for establishing ecosystem management goals, how to develop and interpret management goals for an ecosystem-level risk assessment, how to select and define assessment endpoints, how to develop conceptual models for watershed ecosystems with multiple stressors, when and how to define measures and data that will be used in the assessment, and the explicit need for analysis plans.

8.3.3.8. *Reviews and Current Status*

In May 1994, the Risk Assessment Forum Ecorisk Oversight Committee held a peer review of the draft problems formulations. Substantial discussion at that review centered on the generation of management goals for the watershed and their interpretation into assessment endpoints. The Risk Assessment Forum organized a second peer review in September 1994 that focused on the analysis plans generated from conceptual model development. Significant discussion centered on aspects of the risk assessment process that were changing as a result of case study development. Throughout development, case study drafts have undergone technical peer review by independent professionals knowledgeable about the watershed. In July 1996, the "process" and "lessons learned" and draft "planning and problem formulation" sections of the five case studies were presented to the EPA Science Advisory Board (SAB) for advice on work in progress. The results of that peer review are published and available to the public on the SAB Website (http://www.epa.gov/sab) as report number EPA-SAB-EPEC-ADV97-001. Based on feedback, the case study teams continue to refine work on problem formulation and are moving into analysis and risk characterization. Many of the teams are reconfiguring to ensure that adequate expertise is on the teams for the next phase. Some teams have obtained substantial grant and extramural funds to expand and improve the risk assessment based on the success of the first phases of the case study work. It is anticipated that an additional 2 years will be necessary to complete the full ecological risk assessment and finalize ecosystem-level guidance.

8.3.4. Examples of U.S. Department of Defense Activities in Ecological Assessments

Ecosystem management was adopted by the U.S. military in recognition of the U.S. Department of Defense's (DoD) responsibility as a manager of public trust resources that encompass 25 million acres. It also was recognized that responsible management with a long-term perspective will ensure the continuing availability of training resources, thereby enhancing the sustainability of the military's readiness mission. The Army's Integrated Training Area Management Program, implemented on more than 60 installations nationwide, is an excellent example of the military's efforts to integrate land management objectives with combat requirements through standard methods for monitoring land condition and trends, managing training lands to their carrying capacities, and rehabilitating resources toward a natural state of biodiversity. Within the Army Corps of Engineers Civil Works Program, which is responsible for managing an additional 12 million acres of Federal lands and waters, there is a long history of cumulative impact assessment of watersheds that is now helping to develop risk-based approaches in many regions.

An excellent handbook for military resource managers, *Conserving Biodiversity on Military Lands*, was recently published by DoD and the Nature Conservancy. In addition, the

Army published *Tri-Service Procedural Guidelines for Ecological Risk Assessment* in June 1996, which provides cost-effective tiered procedures with which to coordinate the defense ecological risk assessment efforts of contractors and follows the paradigm put forward in EPA's Framework for Ecological Risk Assessment (U.S. EPA, 1992).

8.3.4.1. *DoD's Ecosystem Management Policy*

Initial DoD guidance established the goal of ecosystem management to balance sustainable human activities, such as the support of DoD missions, with the maintenance and improvement of native biological diversity. Ecosystem management is a balance of ecology, economics, and social values. Partnering and public involvement are stipulated as means to achieving shared goals and making decisions. Goodman (1994) outlined 10 ecosystem management principles and guidelines, which can be summarized in four general themes: ecological approach, stakeholder involvement and collaboration, scientific and field-tested information, and adaptive management. This guidance was formalized in 1996 (DoD Instruction 4715.3, Environmental Conservation Program, May 3, 1996). The following examples illustrate how the military services and DoD are making strides toward full implementation of ecosystem management.

8.3.4.2. *Site Examples*

At Camp Pendleton, California, a project entitled Alternative Futures for the Region is to "examine the connections between urban, suburban, and rural development and the consequent stresses on native habitats and biodiversity." The study poses an important question: How will urban and suburban growth and change that is forecast and planned in the rapidly developing area between San Diego and Los Angeles influence biodiversity? The question is particularly relevant for Camp Pendleton because it constitutes the largest unbuilt segment of land on the southern California coastline and one of the most biologically diverse environments in the United States. Given its position and cache of unbuilt land, Camp Pendleton is central to maintaining the long-term biodiversity of the region. Camp Pendleton plays a key role in the connectivity of the region's ecosystems and over the long term faces the risk of becoming a "habitat island" for species. Camp Pendleton is also key to the military's readiness mission, being the only facility on the West Coast where amphibious assault maneuvers can be practiced. Camp Pendleton resource managers believe that a regional perspective is necessary if a true ecological perspective is to be achieved and that an ecological perspective enhances the long-term readiness mission. The project asks, "Can appropriate management of biodiversity and landscape planning allow the military to more effectively manage its property and efficiently fulfill its mission?" From the Camp Pendleton perspective it asks, "How might issues of biodiversity affect or influence land management activities of the camp?" and "How might future development or conservation ‘upstream’ from Camp Pendleton influence hydrology, ecosystems, and biodiversity on the base and thus potentially influence its primary mission of training?”

In the Chesapeake Bay Program (CBP), each Federal agency commits to managing the Chesapeake Bay watershed as a cohesive ecosystem and to working together and with EPA, States, and other parties to achieve the goals of the agreement. DoD is the lead agency in two key areas: (1) a commitment to upgrade all of its wastewater treatment plants and (2) inclusion of ecological value information in the decision-making process for the disposal of closed Federal facilities. In June 1994, the Navy was designated as the DoD lead in the CBP. Currently, 65 military installations are in the watershed, ranging from small radio transmitter facilities to large industrial and operational installations. The Navy is coordinating with Federal agencies on pollution prevention assessments and is coordinating with the other services to implement the DoD commitments to the agreement of Federal agencies on ecosystem management in the Chesapeake Bay.

At the Mojave Desert Ecosystem Initiative (MDEI), is a project led by the U.S. Army, peer-reviewed science is used to support land management decisions. The project goal is development and implementation of a database to facilitate collection, storage, transfer, sharing, and analysis of information regarding inventories, resource assessments, scientific documentation, and land management by all Federal, State, and local agencies and other interested parties. Ultimately, a queryable database will provide land managers and resource specialists with the tools for attempting to create a regional-scale database to affect dynamic, sustainable ecosystem management. MDEI is an important example of DoD’s ecosystem management activities for several reasons: (1) It is an attempt to provide uniform data coverage across an entire scientifically defined ecoregion, regardless of political or administrative boundaries; (2) data collection, interpretation, documentation, and sharing will be a significant tool used for integrated planning and decision; (3) it provides an important model for sharing, integration, and use of data for ecosystem management purposes by a broad and varied group of participants; and (4) DoD’s military trainers have been effectively integrated into the MDEI’s program.

Adaptive management means the ability to change management structures and protocols to adjust to new or enhanced understandings advanced by the scientific community. Eglin Air Force Base, a 463,000-acre facility near Pensacola, FL, is home to the largest remaining longleaf pine system. Eglin and the surrounding landscape contain 153 rare species, including 13 that are federally listed, and many exceptional occurrences of imperiled natural communities. In partnership with the Nature Conservancy and 30 other organizations, Eglin has developed an ambitious ecosystem management program featuring an adaptive approach. Among the natural resource management program’s most important goals is to restore and maintain the resiliency of native species and ecosystems. Eglin’s military and natural resource management staff believe this approach best provides the broadest array of options for pursuing the base's military mission of testing conventional weapons and munitions. As it is being practiced at Eglin, adaptive management is an integrated, science-driven, and policy-based set of methods and principles for grappling with regional-scale environmental management problems. It seeks to answer two fundamental questions: (1) How do ecosystems change, and (2) how do institutions learn and adapt? Its goal is to integrate knowledge of ecosystem behavior with the policy processes of human institutions and to create learning institutions that can adapt to ecological and social change. With highly unique and high-value posts, camps, and stations, or "habitat islands" in the context of this report, DoD and the U.S. military services will continue to partner with neighboring ecosystem managers, experts, and the public to sustain our Nation's ecosystems for present and future generations.

8.4. RISK ASSESSMENT METHODOLOGY DEVELOPMENT

8.4.1. Expanded Use of the EPA Guidelines

Several agencies have gained experience with ecosystem assessments in recent years. These assessments have varied in scope, cost, and specificity of problems addressed. The agencies and scientists involved have learned lessons along the way, and there is general consensus that the utility of the assessments has improved as experience has been gained. Likewise, practitioners believe that individual assessments should be tailored to address the specific issues and circumstances generating the need for the particular assessment. However, as the need for ecosystem assessments appears likely to continue or expand, continuation of a completely "hand-crafted" approach is not efficient, will overuse available scientific resources, and will not sustain improvement in the assessment craft. We believe expanded use of the EPA Guidelines for Ecological Risk Assessment (U.S. EPA, 1998) offers an opportunity for several agencies to improve the efficiency and utility of ecosystem assessments. While the guidelines were developed for EPA use, judicious use by other agencies can provide government-wide benefits.

Ecosystem assessments do not focus on adverse impacts. In fact, their main focus is to provide comprehensive, integrated information to assist with planning and decision making in an ecosystem context. The EPA guidelines are designed to evaluate the likelihood of adverse effects because they are based on a risk assessment paradigm. The conceptual impasse between ecosystem assessments, which do not have an a priori focus on adverse impacts, and the EPA ecological risk assessment guidelines, which do have an a priori focus on adverse effects, is more apparent than real. Sustainability is the goal of ecosystem management, and the EPA guidelines specifically address methodologies for translating sustainability goals to risk assessment endpoints.

Dialog among parties interested in ecosystem assessment would benefit from an agreement on general long-term goals for ecosystem management, such as sustainability, and the translation of those goals to endpoints amenable to ecological risk assessment approaches. Scientists and/or risk assessors should be involved as facilitators of this dialog while avoiding a role as determiners of the goals and endpoints. Benefits for decision makers and other interested parties will be greater accuracy, clarity, and precision of scientific information available for decision making. Benefits for ecosystem assessment scientists and/or risk assessors are clarity of expectations and lessening of end product controversy.

Flexibility and rigor need to be balanced when use of the EPA guidelines is expanded for application to ecosystem assessment. Traditional risk assessments require data and process rules that are simply not available for most ecosystem assessments. The EPA guidelines clearly recognize the need to adjust risk assessment data rigor to the information available. The guidelines are sufficiently flexible for application to most ecosystem assessments. Principals responsible for ecosystem assessments need to embrace this flexibility while striving to retain as much rigor as possible. Expanded use of the EPA guidelines will increase the value of the Agency's investment in producing them while simultaneously increasing the value of ecosystem assessments that utilize them. Agencies responsible for ecosystem assessments and other ecosystem management activities should seek to understand the EPA guidelines and expand their use. EPA should actively seek to transfer guideline technologies to agencies with ecosystem management responsibilities and expand their use.

8.4.2. Technical and Research Challenges

Ecosystem management is a complex topic that contains a variety of challenges. Ecosystem management needs to be based on sound scientific studies and assessments. However, it also needs to reflect societal values and issues, political and economic concerns, and the decisions need to be legally defensible. Challenges include better linkages of research and technical information to the way society makes decisions in general and how ecosystem management is implemented in particular. Developing effective methods to communicate science and management options and consequences to the public, decision makers, and other stakeholders is a critical need. Successful partnerships between elected officials, the public, interested parties, and scientists have produced effective management programs for the Chesapeake Bay, south Florida, and other regional programs. The experiences gained from these partnerships need to be applied to other regional programs.

8.5. RISK ASSESSMENT IN ECOSYSTEM MANAGEMENT DECISION MAKING

Ecosystem management is the continuous process of holistically managing the physical, biological, and human components of ecosystems. The concepts underlying risk management are relatively straightforward (Marcot, 1986; Bartel et al., 1992; Burgman et al., 1993; Covello and Merkhofer, 1993; Morgan et al., 1990; Lackey, 1994; Suter, 1993). However, the joint application of the ecosystem and risk management concepts in a complex of ecological, organizational, and sociological processes is quite difficult.

8.5.1. The Risk Management Cycle and Ecosystem Management

Risk assessment is part of a cycle of processes that make up risk management. Ecological risk assessment is described in earlier sections of this document. Potential application of the risk management process to ecosystem management would involve eight phases:

1. **Hazard identification**—identifying human actions or natural events, the conditions under which they could potentially produce adverse effects, and the parts of the ecosystem that might be affected.

2. **Risk assessment**—characterizing risks imposed by some proposed action by estimating magnitudes of potential loss, exposure pathways, and likelihoods of occurrence.

3. **Evaluation**—judging the relative acceptability of assessed risks in light of policies, standards, organizational or cultural norms, public opinion, and other expressions of human values. Also, comparing different risks for their relative contribution to the overall level of severity.

4. **Adjustment**—choosing strategies for modifying, avoiding, accepting, or otherwise dealing with the risk profile of proposed actions or likely natural events. These choices involve comparing risk adjustment benefits and costs of various strategies and policy instruments and making difficult tradeoffs among risks and costs.

5. **Implementation**—interpreting the strategy mix in practical standards, guidelines, and incentive systems.

6. **Monitoring**—tracking the effectiveness of the risk adjustment strategies by measuring exposure pathways and risk endpoints sensing for “signal” events that could trigger adaptive responses.

7. **Adaptive Management**—strategies can be implemented through modifications in the proposed actions, mitigations for particular risks, or responses under a planned adaptive management program (Holling, 1978; Walters, 1986).

8. **Risk communication**—translating the results of one phase to another among ecosystem managers, scientists, policy makers, and the public. The traditional view of risk

communication was of a one-way flow of technical information from experts to the public. Recent approaches emphasize multiway communication with an emphasis on understanding the mental models and belief systems on which people judge the acceptability of risks. For the risk management cycle to work successfully, risk communication—clarity, completeness, accuracy, and compatibility with information processing styles—needs to be built into every phase of the cycle.

While these eight phases share some important similarities with the Ecological Risk Assessment Framework, as described earlier in this document, differences are illustrative of the gaps that currently exist between the framework and application of risk management in ecosystem management.

8.5.2. Risk Management and Decision Quality

The effectiveness of the cycle depends in part on the quality of the human judgments and decisions that support it. A high-quality decision is one that (1) solves the correct problem; (2) clearly describes the problem, criteria, and alternatives to the decision maker; (3) generates and evaluates many relevant alternatives; (4) makes choices consistent with criteria and information; and (5) provides for learning that will improve future decisions.

Most successful attempts to improve decision making have involved better organizing and structuring of basic cognitive tasks. Kleindorfer et al. (1993), Dawes (1988), Bazerman (1994), and other decision scientists contend that unstructured tasks are subject to many biases and illusions. Generic decision tasks include (1) process mapping, (2) problem framing, (3) intelligence gathering, (4) evaluation and choice, and (5) learning from feedback. Each of these tasks are subject to unique biases and opportunities for improvement.

Risk management involves decisions about how to reduce probabilities, lower potential losses, interrupt exposure pathways, or collect information to better predict events (MacCrimmon and Wehrung, 1986; Head and Horn, 1991). Each phase of the risk management cycle corresponds to one or more generic decision tasks. The cycle itself is a process map that lays out a sequence of steps and prescribes methodologies and protocols. Hazard identification is a problem-framing and intelligence-gathering task. Risk assessment takes these tasks to higher levels of rigor by requiring probabilistic judgments and analysis of complex pathways. Risk evaluation and adjustment are tradeoff evaluation and choice tasks. Risk monitoring is an intelligence-gathering and learning task.

8.5.3. Risk Assessment as a Decision Aid

As a decision-aiding tool, risk assessment can be judged by six criteria (Covello and Merkhofer, 1993): (1) logical soundness, (2) completeness, (3) accuracy, (4) acceptability, (5) practicality, and (6) effectiveness. The first three criteria are measures of scientific discipline; the last three relate to the users of the assessments' outputs.

Logical soundness is the degree to which the assessment conforms with fundamental theoretical assumptions of basic science, the specific field, and the laws of probability. Completeness refers to whether the assessment accounts for all considerations and scenarios that are relevant to a reasonable choice of policies. Accuracy is whether the assessment correctly describes sources of uncertainty, the probability of their events, and their effects. Sources of inaccuracy include biases and errors in data collection, model specification, and expert judgment, as well as inappropriate application of modeling methods. Inaccuracies can be minimized by sensitivity testing, peer review, and comparison with other assessments or empirical patterns. Acceptability is whether decision makers understand the assessment and find it believable. Barriers to acceptability include lack of public credibility of risk experts, experts' limited understanding of public risk perceptions, and failures to disclose limitations and uncertainties. Credibility problems stem from instability of results under different assumptions and data, complexity of outputs, overuse of technical jargon, invasion of assessment results with advocacy for a risk adjustment option, and lack of trust for the agency doing the assessment. One ironic barrier to acceptability is how uncertainty is displayed. Because humans prefer certainty in answers and predictions, even if they are illusory, risk assessments that describe large degrees of uncertainty tend to be rejected. When risk assessors are most candid about environmental uncertainties, the risk manager or public is likely to be most disappointed because the assessors cannot be definite. If risk assessors ignore or obscure uncertainties and gives unambiguous predictions and advice, their credibility is damaged, especially if the risky event actually occurs (Carpenter, 1993). Practicality relates to whether the assessment can be employed in a real-world environment with deadlines and limited resources and information. Risk assessments usually require interdisciplinary teams, iterations, and many interlocking steps. Risk assessments, especially large-scale assessments, need to be well managed; scientists who serve on assessment teams do not have the inclination or abilities to manage product-driven efforts. Too many risk assessments evolve into piecemeal research projects, with individual scientists pursuing their own subjects and then trying to assemble what they have as the deadline nears.

The effectiveness of a risk assessment is ultimately how much it improves the risk adjustment decision making in the ecosystem management organization. A risk assessment does not stand alone as an estimate, an analysis, or a report, but is actually part of a way of thinking. Using probabilistic information in making decisions is not easy or natural for most human beings.

Most people focus disproportionately on magnitudes of dire outcomes, almost ignoring probability information. People have many automatic or routine ways of dealing with risk that can substitute for analyzing risks. Such behaviors include delaying the decision, delegating or otherwise transferring the risk, ignoring uncertainties, treating uncertainties as if they were certain, collecting information, modifying the management alternatives, buying insurance, making contingency plans, and setting performance standards. If followed without any knowledge of the nature or the degree of the risk being managed, these strategies can misallocate intellectual, financial, and physical resources.

Many still approach risk assessment as a way of justifying and documenting decisions that are already made. To these persons, a good risk assessment will be disappointing because it will expose many incorrect and unfounded assumptions.

8.5.4. Expert Judgment in Risk Management

Quality in professional, or so-called "expert," judgment is an important element of decision quality, especially when there are no precedent events or data, and statistical evaluation is not possible. In these situations, assessment quality may be gauged more on how the judgment mobilizes knowledge, both theoretical and practical, to estimate effects and how the process advances and contributes to the decision process.

Expert judgments of ecological structure and stressor responses enter into the specification of measurement endpoints and the estimation of likelihoods and severities. Judgments of acceptability of risks enter into the risk evaluation phase; judgments of managerial feasibility are the basis for selecting risk adjustment actions. Quality judgments rationally use scientific and other sources of information and are expressed in ways that can be understood and used by decision makers and stakeholders.

Quality expert judgments are important sources of information in risk assessment and risk adjustment. Risk assessment is a form of judgmental hypothesis testing. The null hypothesis is that there is no risk; alternative hypotheses are that the risk may be at various levels. If the risk assessor judges that there is a risk, efforts may be made to adjust it. If the event that creates the loss never actually occurs, the risk management process has made a false-positive error and incurred unnecessary costs. If the expert judges that there is no risk and the event actually occurs, there has been a false-negative error with losses that are perhaps unacceptably high. A good risk management program will attempt to minimize the combination of false positives and false negatives. The symmetry of the loss and cost distributions should guide the level of effort put into assessment and adjustment strategies. Where false-negative losses overwhelm false-positive costs, it is better to invest in more sophisticated assessment processes and more stringent risk adjustments.

Three types of bias influence expert judgments. Task bias is caused by the improper definitions of events or initiating conditions leading the assessor astray. Conceptual biases include motivational biases (wishful thinking or advocacy) and cognitive biases (systematic patterns of thinking that do not allow full expression of subject matter knowledge in probability form). Expert judgments can be improved by structuring elicitation processes to keep judgments relatively free of these biases and to fully reflect the knowledge of the experts. Process guidelines include avoiding experts who have agendas or preconceived notions, obtaining estimates from several sources, challenging experts to explain their rationale, encouraging experts to move estimates from their initial estimate "anchors," requiring experts to provide degrees of uncertainty, checking estimates against any records of similar losses, and removing sources of distraction and motivational bias from the elicitation environment (Cleaves, 1994).

8.5.5. Risk Evaluation, Adjustment, and Decision Quality

The risk manager should fully evaluate a range of options for managing risks, including incentive-based and other flexible policies for allowing managers to assess and adjust risk according to site-specific information, experience, and knowledge. Risk policy is composed of rules and standards and other instruments that signal which risks are most important and what levels of those risks are acceptable. Protection standards are written to ensure particular behaviors of human managers toward ecosystem components. Standards limit improper outside factors from influencing resource management decisions. Standards convert probabilistic choice into a deterministic rule (Keeney, 1983). Whoever develops standards makes critical tradeoffs: those who accept or implement standards may not have the same degree of discretion. Some flexibility is beneficial for sites at smaller scales of analysis and choice. Standards that attempt to minimize magnitude discourage managers from basing their decisions on the relationship of magnitude and probability. Standards that consider probability as well as magnitude may provide a useful tool for risk managers.

8.5.6. Risk Communication and Decision Quality

Implementing risk management in an ecosystem management context depends on clear communication among participants in the risk management cycle and on public support. The public will not accept risk assessments or management policies just because they represent expert judgment. Underlying psychological attributes of risk perception influence risk information. These attributes include (1) voluntariness or controllability, (2) dread or vividness, (3) familiarity with the outcome, (4) extent (degree of catastrophe) in the losses, and (5) future generational impacts (Covello et al., 1986; Sandman, 1985; Slovic, 1987; Cross, 1994). People focus on these attributes to adjust their judgments of magnitude, frequency, and degree of exposure. Some events have a high “signal” value in that they may symbolize the potential of more serious risks in the future.

Involving the public in risk management is the best way to better understand and work with risk perceptions. Many techniques such as focus group interviewing, group facilitation, and alternative dispute resolution can be applied to public involvement in risk assessment. Part of this effort should be devoted to helping the public recognize and contribute to decision quality. All parties should be able to ask questions about decision quality: What perspectives are involved? What factors have been omitted? Are major uncertainties quantified and explained? Have sensitivity analyses been conducted? How are the risk assessment and risk adjustment tasks separated to minimize bias? An informed public will appreciate honest efforts to characterize risks, be more creative in suggesting risk policies, and be less inclined to reject assessment results.

8.6. NEXT STEPS

This chapter has provided some examples of ecosystem assessments for ecosystem management, views of how risk assessment methodologies could contribute to more efficient ecosystem assessments, and a description of how improved ecosystem management decision making would be the result of hybridizing ecological risk and ecosystem assessments. The following “next steps” would help natural resource agencies move along that pathway.

- Link ecological risk assessment and ecosystem management to improve organizational and analytical consistency in support of multiple scales of resource management.

- Expand the use of EPA’s Guidelines for Ecological Risk Assessments (U.S. EPA, 1998) across agencies to improve the efficiency and utility of ecosystem assessments.

- Improve valuation technology to provide better definition of societal values and preferences and to better achieve awareness and active involvement of a diverse array of stakeholders.

- Link ecosystem assessments using common information themes and protocols that provide analyses of ecosystem process, structure, and function at multiple temporal and spatial scales.

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9. THE USE OF ECOLOGICAL RISK ASSESSMENT FOLLOWING THE ACCIDENTAL RELEASE OF CHEMICALS

9.1. SUMMARY

The application of an ecological risk assessment to the accidental release of chemicals is an iterative process. For sites where chemical release is relatively frequent (harbors and chemical transfer areas), planning for an accidental release of chemicals is common. These plans address the chemical types and quantities to expect, personnel, and equipment needs. The ecological risk paradigm problem formulation phase provides the structure for a planning process that asks the question, "What are we trying to protect?" The analysis and risk characterization phases, in a response plan, are qualitative in nature but relate to remediation of ecological impacts. For releases at sites where no plans exist, the ecological risk assessment is qualitative in nature, such as limiting the size and degree to which an area is impacted. As resource managers and trustees respond to the release, the risk to natural resources is evaluated in detail. The required remediation to reduce the risk and/or restoration of the resource is specified. This chapter briefly reviews several environmental laws that deal with accidental releases and Federal Government responsibilities and response to them. In addition, information is provided on Federal and State agency trustees for natural resources, natural resource damage assessments, and the role of trustee agencies in working with the on-scene spill coordinator.

The case study describes the accidental release of contaminated dredged material off Charleston Harbor, SC. About 2,500 tons of dredged material contaminated with dioxin, PCBs, and other chemicals was released. The response team identified the resources to protect and the data requirements, which were similar to the problem formulation phase in an ecological risk assessment. An analysis plan was developed to determine the degree of contamination of the dredged material and seawater in the barge. Various criteria were developed to determine areas of sediment to clean up and whether release of seawater from the ship was permitted. These activities characterized the risk to the affected resources and put forward remediation alternatives to the risk manager.

Risk assessors and risk managers can follow ecological risk assessment steps as a guide in developing spill contingency plans. This would lead to better responses to accidental chemical releases and to greater protection for sensitive ecological resources.

9.2. INTRODUCTION AND LEGISLATION

When an accidental release of a chemical occurs, the public often feels that the only acceptable response is immediate and total removal of the chemical and restoration of the environment. Since such action is rarely, if ever, achievable, these expectations are not met, and the public is generally disappointed by the Government's action. The ecological risk assessment process, by encouraging a structured approach to problem solving and greater public involvement in the process, can help this situation. By definition, emergency or accidental releases are unscheduled and unplanned. Therefore, the principles of ecological risk assessment must be incorporated in advance into the processes that determine the manner in which an agency will respond to a release. Strategies to protect and restore sensitive ecological resources must be developed before an accidental release occurs.

Several key environmental laws deal with accidental releases and dictate how Federal agencies are to respond. An important aspect of these laws deals with the concept of "trust resources," Federal and State trustees, and natural resource damage assessments.

The **Comprehensive Environmental Restoration, Compensation, and Liability Act (CERCLA)** and the National Contingency Plan (NCP) require that the responding agency coordinate with the natural resources trustees on natural resource issues to understand the policies and legislative requirements the trustee groups may have.

The portions of the **Fish and Wildlife Coordination Act** (16 U.S.C. 661-667e, as amended) that directly relate to hazardous material and spill response are the amendments enacted in 1946 that require consultation with the U.S. Fish and Wildlife Service and the fish and wildlife agencies of the State where the "waters of any stream or other body of water are proposed or authorized, permitted or licensed to be impounded, diverted…or otherwise controlled or modified" by any agency under a Federal permit or license. Consultation is to be initiated for the purpose of "preventing loss of and damage to wildlife resources."

The **Refuge Administration Act** (16 U.S.C. 668dd-668e, as amended) governs the administration and resource management issues on lands in the U.S. Fish and Wildlife Service Refuge System. The portion of the act that may play an important role during a spill or release relates to the function of the refuge and the purpose for which the refuge was created. Activities related to refuge lands must be consistent and compatible with the major purposes of the refuge. Therefore, assessment and characterization of the spill may be directly influenced by the function of the refuge.

The **Endangered Species Act** (16 U.S.C. 1531 et seq.) regulates a wide range of activities affecting plants, animals, and their habitats designated as endangered or threatened. Section 7 outlines the procedures for Federal interagency cooperation to conserve federally listed species and designated critical habitats.

The act has a provision for proactive conservation efforts by Federal agencies. Section 7(a)(1) directs all Federal agencies to utilize their authorities in furtherance of the purposes of the act by carrying out programs for the conservation of species listed pursuant to the act. This section makes it clear that all Federal agencies should participate in the conservation and recovery of listed threatened and endangered species. Under this provision, Federal agencies often enter into partnerships and Memoranda of Understandings with the U.S. Fish and Wildlife Service or the National Marine Fisheries Service for implementing and funding conservation agreements, management plans, and recovery plans for listed species.

Section 7(a)(2) states that each Federal agency shall, in consultation with the Secretary (of Interior and Commerce), ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. In fulfilling these requirements, each agency must use the best scientific and commercial data available. This section of the act defines the consultation process, which is further developed in regulations promulgated at 50 CFR 402.

The **Migratory Bird Treaty Act** (16 U.S.C. 703-712; 703-712, as amended) established a prohibition, unless a permit is issued, to kill, attempt to take, possess, sell, or capture any migratory bird. The act protects migratory birds and any part, nest, or egg. The U.S. Fish and Wildlife Service administers this act and serves as the lead agency in the protection of these animals. The act applies to migratory birds affected in spills and hazardous releases.

Many other statutes and executive orders apply in the event of a spill; however, the above legislation outlines the major regulations that govern response activities and related operations. Each agency has implemented response planning in a slightly different manner; therefore, the exact response will be different depending on which agency has lead responsibility.

9.3. USE OF THE RISK ASSESSMENT PROCESS IN ACCIDENTAL RELEASES

CERCLA section 107(a)(4)(c) establishes liability for damages for injury to, destruction of, or loss of natural resources, including the reasonable costs of assessing such injury, destruction, or loss. Natural resources are defined to include land, fish, wildlife, biota, air, water, ground water, and drinking water supplies and other resources belonging to, managed by, held in trust by, appertaining to, or otherwise controlled by the United States, any State or local government, any foreign government, or any Indian tribe. The statute also directs the President, through designated representatives, to act on behalf of the public as a trustee of such natural resources. Natural resource damage assessment is the process used to assess damages to natural resources from releases of oil or hazardous substances and to obtain compensation to restore injured natural resources and their services. The damage assessment process used by natural resource trustee agencies is guided by a series of regulations. Under the NCP, natural resource trustees are defined to include States, tribes, and five Federal agencies (the Departments of Commerce, Interior, Agriculture, Energy, and Defense). Note that EPA is not a trustee for natural resources. (For further discussion, see Section 5.2.5.)

Natural resource trustees have technical expertise that can improve design of ecological risk assessment studies, facilitate the interpretation of data and results, improve remedy selection and design, and design and implement more effective remedial restoration. By incorporating natural resource concerns into the remedial process, residual injury (and the associated liability of the responsible parties) can be minimized, and the need for damage assessment activities can be eliminated.

Numerous books, Government documents, and peer-reviewed and gray literature have addressed the issues surrounding ecological risk assessment, and the process and procedural guidelines have been presented in many forums by multiple Government agencies (Wentsel et al., 1996; U.S. EPA, 1992, 1994, 1996) and private individuals (Suter et al., 1983; Barnthouse et al., 1990; Calabrese and Baldwin, 1993). Currently, little guidance exists that specifically identifies the role of ecological risk assessment in an accidental release situation. Many of the processes outlined in the above documents may have a direct bearing on spill and hazardous waste site assessment and ecological evaluations. Many of the problems associated with the use of ecological risk assessment at a hazardous release or spill involve the need for protecting human health and safety in an expeditious manner, so there is not adequate time to implement an ecological risk assessment in the traditional sense. Therefore, the ecological risk assessment process must be evaluated specifically for an emergency planning response.

In terms of the ecological risk assessment process, natural resource managers must (1) know the location of important resources, however they are defined, and be able to identify probable threats to the resources of concern (problem formulation); (2) identify the possible impacts from the material that might be released (exposure characterization); and (3) know the probable ecological impacts to the species of interest (risk characterization). Discussion between the resource managers and the risk assessors will lead to a plan for protection of the biological resources, including determining what the tradeoffs might be for different spill scenarios (risk management). If the outcome of the management alternatives does not adequately protect the biological resources, then alternatives can be considered and discussion continued until an adequate response plan is established. The value of the ecological risk assessment process exists in both preparedness planning and in the actual site-specific assessment of a given spill or release.

9.4. EXAMPLES OF ACCIDENTAL RELEASES

The dynamics of an emergency situation do not lend themselves to drafting written plans leading to a site-specific ecological risk assessment. Typically, decisions must be made rapidly, with every practical effort being made to coordinate inputs from many parties. Following reporting of a spill or accidental release, a Federal on-scene coordinator (FOSC) takes charge. In the case of a spill in inland areas, the FOSC is usually from the EPA Regional Office. For spills in the marine or estuarine environment, the FOSC is from the Coast Guard. At the request of the FOSC, usually depending on the nature and size of the event, a natural resource trustee (either Federal or State or both) is responsible for providing liaison with the FOSC in order to represent fish, wildlife, and sensitive environmental concerns relative to response activities.

The trustee will provide immediate input and identify the areas of greater ecological risk to the FOSC. Recommendations relative to the protection of and/or response to these sensitive areas will be submitted to the FOSC to mitigate any adverse ecological impact. The recommendations also may initiate the collection of collateral data to determine if it is necessary to develop a restoration plan. Biotic and abiotic collections may be required to establish, quantify, and document adverse effect and pathways caused by the discharge or release. These activities equate to problem formulation in the ecological risk assessment process and the identification of complete exposure pathways.

One case study and several spills are presented that depict the range of planning and management activities that have occurred in response to accidental releases.

9.4.1. Case Study: *Patricia Sheridan* Release of Contaminated Dredge Material

At 1:40 a.m. on October 12, 1995, the 106-meter-long barge *Patricia Sheridan* was intentionally grounded because of an extreme list developed during a storm approximately 2 miles seaward of Charleston Harbor and approximately 150 meters southwest from a Federal navigation channel. The barge was carrying approximately 12,000 tons of dredge material contaminated with dioxin and other hazardous substances from the Howland Hook Marine Terminal, Staten Island, NY, to an off-loading facility in Corpus Christi, TX, for subsequent rail car transport to a disposal facility in Utah. While the barge was listing in approximately 10 meters of water, two hatch covers opened over the cargo. During the storm and, to some degree, subsequently, an estimated 2,500 tons of dredged material spilled into the sea. Initially, the U.S. Coast Guard responded to the incident as a salvage operation because of navigational safety concerns. Most natural resource trustees were notified of the release on October 12.

The natural resource trustees considered a number of concerns in developing an evaluation of potential risks to public welfare, including ecological risk, arising from this incident. Screening-level values for the following environmental media were determined:

- **Surface water:** This concern stemmed from the discharge of dioxin-contaminated effluent water generated during the raising of the sunken barge. State and Federal water quality criteria for the protection of aquatic organisms were the measurement endpoint. Promulgated criteria/standards for dioxin do not exist; however, a chronic toxicity value for marine organisms for total polychlorinated biphenyls (PCBs) is 0.03 µg/L.

- **Sediment:** Promulgated criteria/standards for dioxin, PCBs, or metals do not exist; however, in lieu of sufficient site-specific data on toxicity, resource agencies rely on other widely accepted screening guides, including effects range low (ERL), effects range medium (ERM), and apparent effects thresholds (AETs).

- **Biological tissues:** Promulgated criteria/standards for fish or shellfish or other wildlife for ecological effects do not exist. In lieu of direct effects data, resource agencies may rely on contaminant values in wildlife that if consumed by humans would pose unacceptable risk to humans, for example, Food and Drug Administration action and tolerance levels. While concentrations below these levels are not considered by resource agencies as necessarily protective of ecological receptors, higher concentrations are suggestive of harm. In addition, if these concentrations are found in fish, shellfish, or wildlife, the potential commercial, recreational, or subsistence value (i.e., natural resource services) of these resources is significantly diminished.

The potential public welfare elements at risk were identified as:

- Recreational fisheries

- Nonrecreational fish, shellfish, and other aquatic life

- Ongoing and potential Federal/State actions, including Superfund sites, affected by inadequate characterization of extent of contamination and risk

- Marine transportation services

- Designated ocean dredge materials disposal site
- Resources beyond the 12-mile territorial sea

- Resources beyond the 200-meter economic exclusion zone.

The inclusion of professional and experienced ecological risk assessors during emergency and time-critical incidents generally should be sufficient to account for all the prescribed elements considered in a remedial setting.

On October 13, State and Federal natural resource trustees received a copy of the Department of the Army Corps of Engineers (ACE) dredging permit for the Howland Hook Marine Terminal and accompanying sediment sample and bioassessment analysis data that served as the basis for the permit conditions. The data indicated that levels of dioxins, PCBs, and several metals exceeded some ecological effects screening values, such as ERLs and ERMs. However, the permit material provided suggested to the trustees that the primary contaminant of concern was the dioxin congener 2,3,7,8-TCDD. The permit stated, “As a result, the bioassay/bio-accumulation testing for dioxin [2,3,7,8-TCDD] indicates that the proposed dredged material does not meet the criteria for unrestricted ocean disposal." Concentrations for sediment characterization in only three samples analyzed for dioxin ranged from 74 parts per trillion (ppt) to 140 ppt. Test sediment concentrations ranged from 8.5 to 39 ppt. Concentrations above 10 ppt dry weight 2,3,7,8-TCDD toxic equivalents in sediments are considered by some as potentially threatening. The dredge material failed to pass criteria allowing ocean disposal under the Marine Protection, Research and Sanctuaries Act, and consequently permit language stated, "It [dredged material] shall not re-enter ocean waters."

The natural resource trustee agencies, including the South Carolina Department of Marine Resources, the U.S. Fish and Wildlife Service, and NOAA, requested the response agency to treat the incident as a CERCLA release because of its potential threat to public welfare, which included the bioaccumulation/biomagnification potential in natural resources such as fish and shellfish and associated impacts to recreational fishing. In addition, uncontrolled releases of dioxins could confound ongoing CERCLA actions in the Charleston Harbor area, specifically as they might relate to culpability. It was determined that exceeding a reportable quantity was not necessary to initiate a response action.

The *Patricia Sheridan* was 1 of 11 such barges transiting dredge materials from Howland Hook, and no analytical data were known on the specific contents of any single barge load. Because dioxins from the barge may comingle with dioxins already in the immediate environment from other sources, including National Priority List (Superfund) sites, the risk assessors successfully argued that congener-specific data might be the only way to assign culpability. Considering all of these arguments, the response agency requested the potentially responsible party (PRP) to provide such information to characterize the nature of continuation.

The response agency requested an incident-specific regional response team conference to discuss the issue of discharge of the water contained in the cargo hoppers, which was necessary to facilitate salvage. The hoppers contained an estimated 489,000 gallons of seawater. The State of South Carolina stated that its criterion for total dioxin of 1.2 ppq (parts per quadrillion) should not be exceeded in discharge effluent waters. Because no Federal water quality criteria for dioxins existed, the risk assessors considered the State criterion as a screening risk value for marine surface water protection. It was requested that unfiltered water be analyzed, as dioxin would likely be adsorbed to particulates and therefore not be free phase.

A Captain of the Port Order was issued requiring sampling and analysis of sediments for constituents of concern in the area outside the barge. Results indicated that some metals and dioxins released from the barge were now located on the seafloor. The U.S. Coast Guard, with acknowledgment by the trustees, determined that the release represented an imminent and substantial danger to public health and welfare.

Of greatest concern to one trustee agency, NOAA, was the potential contamination of the federally maintained navigational channel. Under the NCP, NOAA's natural resource trusteeship extends to natural resources managed or controlled by other Federal agencies and that are found in, under, or using waters navigable by deep-draft vessels. Given that the ACE manages, controls, and maintains Federal navigation into the Port of Charleston, NOAA expressed concern over the potential threat to transportation services provided by surface waters. Threats included the potential inability of the ACE to continue to dispose dredge materials from the Federal navigational channel at the ocean materials disposal site, possible delays in maintenance dredging associated with the need to find alternative disposal solutions, increased costs associated with disposal at alternative disposal sites, and potential interruptions in commercial and Department of Defense waterborne transportation.

The PRP contract laboratory reported 2,3,7,8-TCDD in barge water at 5.4 ppq and a total dioxin concentration of 10.0 ppq. Again, the State of South Carolina criterion for total dioxin was 1.2 ppq. Therefore, discharge of this water would violate State water quality criteria and potentially present an unacceptable risk to marine aquatic resources.

The FOSC issued an Administrative Order on January 10, 1996, requiring the removal of 3.1 cm of sediments over a 4-acre area on the sea floor. To evaluate the effectiveness of the removal action, the U.S. Coast Guard and the natural resource trustees required pre- and postbiological tissue analyses and postsediment sampling for 17 dioxin congeners. A second round of postbiological tissue sampling, as in the first round of sampling, revealed a lingering potential problem at the site. As a noteworthy anecdote, the sampling identified a wider area of dioxin contamination in the Charleston area offshore waters.

More than 4 acres and approximately 5,460 cubic yards around the grounding site were dredged to remove the upper 3.1 cm of sediment. The preliminary results of the biota sampling were presented by the PRP along with the quality assurance/quality control data. The data demonstrated failure of the response to meet the conditions set by the FOSC in consultation with the trustees. The FOSC ordered that a second set of samples be collected and analyzed. The FOSC ordered the PRP to fulfill the requirements of the Administrative Order by continuing the necessary biota monitoring. A second set of data also failed to meet the conditions set by the trustees and the FOSC. However, the FOSC in consultation with the trustees determined that the cost associated with additional removal would not be justified by reductions in threat, and therefore, the response effort was determined to be ended. The natural resource trustees were now in a position to determine whether or not residual conditions warranted an NRDA action for restoring lost resources and services.

In August 1996, the U.S. Coast Guard consulted with the trustees regarding the second set of biota monitoring data and wrote the PRP that it had met the conditions of the January 10, 1996, Administrative Order and that therefore the emergency response phase "…is hereby rescinded."

This incident demonstrated that although marine accidents may begin as emergency responses, they can develop into time-critical or nontime-critical responses that require greater levels of planning and coordination. In addition, pre- and postsediment and biological tissue sampling enabled the response agency and the natural resource trustees to properly evaluate response effectiveness, a step usually necessary to provide the trustees with sufficient information on which to base a decision for pursuing NRDA action leading to restoration of lost resources or services.

9.4.2. Types of Accidental Releases

9.4.2.1. *John Day River Acid Spill*

On February 8, 1990, a tanker truck owned and operated by Thatcher Trucking Company of Salt Lake City, UT, skidded off Highway 395 and rolled down an embankment into the North Fork of the John Day River in north-central Oregon. The accident occurred near the town of Dale, just south of the Camas Creek Bridge and immediately below the mouth of Camas Creek at river mile (RM) 56.8. The contents of the tanker, approximately 5,000 gallons of 35.2% hydrochloric acid, began leaking through a ruptured diaphragm in the pressure valve. An estimated 3,500 gallons, or 33,500 pounds, of the acid discharged into the river and flowed downstream at an approximate rate of 1 mile per hour, causing substantial change in the acidity of the river.

Natural resource trustees with the authority for managing and protecting natural resources in the impacted area include the Department of the Interior (DOI), represented by the U.S. Fish and Wildlife Service and the Bureau of Indian Affairs; the State of Oregon, represented by the Oregon Department of Fish and Wildlife (ODFW); and the Confederated Tribes of the Umatilla Indian Reservation (CTUIR). Assessment of natural resource injuries and development of a restoration plan was coordinated between the trustees and the Confederated Tribes of the Warm Springs Reservation of Oregon (CTWS).

Historically, the John Day River was one of the most significant anadromous fish-producing rivers in the Columbia River watershed. The John Day River Basin continues to support one of the largest remaining runs of wild spring chinook salmon (*Oncorhynchus tshawytscha*) and summer steelhead trout (*Oncorhynchus mykiss*) with populations estimated to range from 3,000 to 4,000 spring chinook salmon and 30,000 to 35,000 summer steelhead. The basin also supports a population of Pacific lamprey (*Lampetra tridentata*) as well as other indigenous species. The management policy for the John Day River Basin is designed to maintain native wild stocks of salmon and steelhead and to preserve the genetic diversity of the native salmon and steelhead stocks for maximum habitat use and fish production.

The basin also supports a variety of resident fish species, such as rainbow trout (*Oncorhynchus mykiss*), brook trout (*Salvelinus fontinalis*), bull trout (*Salvelinus confluentus*), cutthroat trout (*Salmo clarki*), mountain whitefish (*Prosopium williamsoni*), channel catfish (*Ictalurus punctatus*), and smallmouth bass (*Micropterus dolomieui*). Bull trout are of particular concern because they are a Federal candidate species petitioned for listing as threatened or endangered under the Endangered Species Act. Other resident species common to the area include chiselmouth (*Acrocheilus alutaceus*), suckers (*Catostomus spp.*), redside shiner (*Richardsonius balteatus*), longnose dace (*Rhinichthys cataractae*), sculpins (*Cottus spp.*), and northern squawfish (*Ptychocheilus oregonensis*).

Numerous natural resources within a minimum 12-mile stretch of the North Fork of the John Day River were injured as a result of the hydrochloric acid discharge. The pH of the river was lowered from a normal background level of 8.0 to 2.4 (Oregon Department of Environmental Quality, 1990). Hydrological modeling showed that the river did not have the acid neutralizing capacity to recover to a pH of 6.5 even at RM 15.3, which is 41.5 miles downstream of the spill site. Thus, natural resources under the trusteeship of the DOI, the State of Oregon, the CTUIR, and the CTWS were adversely affected by the acid spill.

The sensitivity of fish to acidic water varies, but pH levels below 6.0 can be detrimental to many species (Haines and Baker, 1986; Gloss and Schofield, 1989; Wiener and Eilers, 1989). Exposure to the acid was manifested in fish by burned, blistered, or discolored skin; singed fins; bleeding gills; loss of scales; cloudy eyes; internal bleeding; and severe behavioral distress. ODFW (1990) and Dougan (1990) estimated 98,000 to 145,000 fish were destroyed, including 4,000 anadromous fish, 300 bull trout, and 9,500 Pacific lamprey. The loss of 300 bull trout in the river is especially critical because the spill may have destroyed a large portion of the adult bull trout population in this area (H. Li, personal communication, 1990). Although bull trout primarily occur in the upper tributaries of the John Day River Basin, they seasonally utilize the North Fork of the John Day River in the winter. The spill occurred at a time when a large portion of the adult bull trout population was probably in the North Fork of the river.

In addition to adult fish, an estimated loss of 50% of the chinook salmon alevins was reported (ODFW, 1990; Dougan, 1990). This estimate was based on a quantitative aquatic invertebrate analysis that showed a 50% loss of invertebrates in the first mile below the spill site. Aquatic invertebrates provide an essential food resource for many species of resident and anadromous fish as well as other species. A reduction in aquatic invertebrate abundance had a short-term impact on food availability. Long-term loss of natural production of salmonid species and complete annihilation of at least one age class of locally spawning salmon and steelhead occurred from the spill. Additionally, although direct mortality of fish was not documented in surveys beyond 12 miles downstream from the spill site, chronic effects most likely occurred in these areas.

Aquatic mammals, waterfowl, and endangered species that utilize the John Day River Basin also may have been directly or indirectly impacted by the spill. Loss of fish from the North Fork John Day River could have affected wintering bald eagles (*Haliaeetus leucocephalus*), mink (*Mustela vison*), and river otter (*Lutra canadensis*) that are known to forage in the river. Peregrine falcons (*Falco peregrinus*; an endangered species) nest in the basin, and numerous waterfowl species use the river, including Canada geese (*Branta canadensis*), common (*Mergus merganser*) and hooded mergansers (*Lophodytes cucullatus*), mallard (*Anas platyrhynchos*), gadwall (*Anas strepera*), American widgeon (*Anas americana*), wood duck (*Aix sponsa*), and green-winged teal (*Anas crecca*). All of these species may have been indirectly affected by the spill through destruction of their food base; changes in foraging, shelter, breeding, and rearing areas; or other factors essential for long-term survival.

In addition to fish and wildlife resources, the river supports significant tourism, hiking, camping, subsistence fishing and trapping, and commercial and sport fisheries. The impacted area also has important cultural and archaeological values to the local Indian tribes. Tribal subsistence fishing in tributaries in the John Day River Basin and mainstem Columbia River provides a culturally important food source for the tribes. Pacific lamprey, salmon, and other indigenous species such as whitefish, suckers, and chiselmouth have been essential food fish for the tribes of the John Day River Basin for centuries. The capacity of the river system to support these consumptive and nonconsumptive activities may be reduced for many years as a result of the spill.

The John Day River Basin is managed to maintain wild salmon populations, with no enhancement through the release of hatchery stock. A management plan has been developed by ODFW and the tribes to oversee this objective. Because of this management policy, no short-term remedial actions, such as restocking with hatchery-reared fish, could be used to restore resources lost during the acid spill. Recovery of damages in the form of habitat restoration actions in the John Day River Basin that are consistent with management plans for the area were sought from the responsible party. Appropriate restoration actions will improve conditions in the river to promote fish and wildlife production lost due to the acid spill. In addition to the mainstem North Fork, restoration efforts should be directed to the tributaries such as the Middle Fork John Day River, Camas Creek, and Desolation Creek. Providing improved habitat for fish will aid in replenishing the injured resources, increase the survivability of fish not killed during the acid spill, and aid in replenishing the natural population by increasing productivity. In addition, restoration projects will increase egg-to-smolt survival, increase smolt-carrying capacity, provide more and better habitat for juvenile fish rearing, and increase pre-spawner survival. Recovery of lost resources will not happen quickly; completion of restoration actions and full recovery of the fish populations could take 10 or more years.

9.4.2.2. North Cape *Oil Spill*

On January 19, 1996, the tug *Scandia* caught fire while it was towing the tank barge *North Cape* in the coastal waters off Rhode Island. The tug was abandoned and storm-force winds grounded it and the barge off Moonstone Beach, approximately 3 miles west of Point Judith, RI. Approximately 820,000 gallons of number 2 fuel oil leaked from the damaged barge, impacting coastal and marine habitats, including a national wildlife refuge and other sensitive areas. Heavy surf hampered efforts to contain the spill, and officials reported that thousands of lobsters, clams, and other invertebrates and hundreds of birds were killed. A 250-square-mile area of Block Island Sound and seven coastal ponds were closed to fishing.

On January 20, 1996, the EPA Environmental Response Team (ERTC) was activated to provide technical assistance to the FOSC. EPA personnel from the Region 1 Emergency Removal Program, the Region 1 Laboratory in Lexington, MA, and the Office of Research and Development (ORD) Laboratory in Narragansett, RI, also responded to provide support to the U.S. Coast Guard, the National Oceanic and Atmospheric Administration, the State of Rhode Island, and DOI to support assessment of the spill. EPA activities were focused on sampling and analyzing sediments, the water column, and aquatic organisms to determine fate and effect of the spilled oil while also providing technical support on methods to contain the released fuel.

Water quality concerns were addressed by a sampling effort conducted jointly by EPA Region 1, ORD-Narragansett, and ERT. The natural resource trustees, both State and Federal, also sampled biota and environmental media and rehabilitated oiled birds. The trustees formed four technical working groups to evaluate injury and identify potential restoration opportunities. Three groups investigated effects to natural resources, including marine communities, salt ponds, and birds. A fourth group (economics) helped the other groups scale injury and restoration, as well as determine economic losses.

There was an intense acute toxicological response in the benthic community in the near-shore area close to the grounding site. Severe weather conditions aggravated the toxicity of the oil via complete entrainment and dispersion of the oil into the water column. There were concentrations of 1 to 6 ppm total petroleum hydrocarbons throughout the water column to depths of 20 meters. The trustees estimated that millions of lobsters, surf clams, crabs, and amphipods were killed. In total, 26 species of finfish and large invertebrates were identified among the dead organisms in beach strandings.

Seven salt ponds were exposed to *North Cape* oil and potentially impacted from the spill. Extensive mortality of infauna (primarily amphipods) occurred in several of the ponds. Winter flounder were exposed to levels of oil that cause sublethal effects and could potentially reduce their reproductive output. Shellfish, including oysters, mussels, and soft-shell clams, were exposed to oil, although acute mortality was limited. Brackish wetlands and salt marsh communities were exposed to oil; however, no significant injury to salt marsh vegetation was measured.

Investigators recovered about 400 dead birds (primarily waterfowl, loons, and grebes). To account for birds that were never found because they sank, drifted out to sea, or were scavenged, the trustees applied a multiplier of 6 to the total number of birds recovered, resulting in an estimate of approximately 2,300 dead birds (nonwater birds were not included in the multiplier). This multiplier was based on a qualitative analysis of factors influencing oil spill-related bird mortality. These factors included the weather conditions, location of the spill, oil characteristics and volume, and number of birds potentially exposed to oiling. The trustees also assessed impacts to the federally threatened piping plover, which breeds on Moonstone Beach. Piping plover productivity at Moonstone Beach dropped 37% in 1996 compared with 1995. Declines in piping plover productivity at Moonstone were in contrast to other sites in Rhode Island, where productivity increased 6% in 1996 compared with 1995.

9.4.2.3. *Conoco Marine Terminal 1,2-Dichloroethane Spill*

In March 1994, Conoco discovered that a pipeline from its marine terminal on the Clooney Loop of the Calcasieu River in Louisiana was leaking 1,2-dichloroethane (EDC). Although the company undertook emergency response operations that it believed were successful, gross EDC contamination was discovered in late May 1994 during routine sediment sampling. This discovery caused Conoco to notify the National Response Center (NRC) of the additional amount of the release.

NOAA provided technical advice to the FOSC, conducted reconnaissance and ecological risk assessment sampling, and worked with the responsible party (Conoco) to review the past work that Conoco had undertaken and the proposed work plan. NOAA also worked to have ecological investigations conducted in the Clooney Loop. These investigations determined that benthic communities probably had been impacted by the release, but that those impacts were localized and not widespread and that the contaminant would attenuate naturally over time. This work reinforced the State’s decision to allow natural degradation to complete restoration of the Clooney Loop rather than requiring extensive dredging. This resulted in a cost savings to Conoco of approximately $20 million.

NOAA assembled the natural resource trustees concerned with the release to facilitate development of a negotiated settlement subsequent to CERCLA removal. The trustees, led by NOAA, began developing a cooperative strategy to assess injuries and acquire compensation.

NOAA continued to participate in the response by reviewing reports, providing advice to the FOSC, and facilitating expeditious cleanup. Conoco presented a proposal at a meeting in March 1995 to use habitat equivalency analysis to scale a restoration project 9 river miles from the Clooney Loop. NOAA worked with the trustees and Conoco to refine and finalize the proposal. As a result, all parties agreed to a project that cost-effectively would restore the natural resources of the Calcasieu estuary harmed by the EDC release.

In June 1996, Conoco and the natural resource trustees signed an agreement that Conoco, through its agent Stream Management, Inc., would restore 41 acres of transitional wetland habitat. Of that total, 4.5 acres will be maintained in perpetuity. This area will provide compensation for the lost 20.7 acre-years of services. The remainder (36.5 acres) will be maintained for 50 years as a natural buffer to protect the ecological functioning of the compensation tract. Conoco and Stream Management have purchased the property, and the final settlement document is in preparation. An environmental assessment, a requirement under the National Environmental Policy Act, was prepared, submitted for public comment, and finalized. Due to NOAA's efforts, an ecologically protective cleanup was expedited, and cost-effective natural resource restoration was begun quickly without resorting to time-consuming, expensive litigation.

9.5. RISK ASSESSMENT METHODOLOGY AS APPLIED TO ACCIDENTAL RELEASES

By evaluating the components of an ecological risk assessment, risk assessors and managers can examine how each element may fit during an accidental release. The intent of the ecological risk assessment is not only to show that there are adverse impacts but also to determine at what levels contaminants can exist in the environment while the ecological system remains protected. The heart of the ecological risk assessment is the problem formulation phase. Problem formulation is composed of several elements, including selecting assessment endpoints, developing a testable hypothesis and a conceptual model, and determining measurement endpoints. Although presented here as a linear process, the problem formulation phase is iterative, and each element affects the others in the process. These elements form the basis of a logic tree that allows the investigator to make logical decisions regarding the remediation or cleanup activity.

Assessment endpoints are essential in the ecological risk assessment and can play an important role both in preparedness and during the actual assessment following a release or spill. Assessment endpoints are defined as "an explicit expression of the environmental value that is to be protected." During a release or during the planning for such an event, the investigator should identify what elements of ecological concern exist. The first priority during a spill or release is to determine habitats that have not yet been impacted but are at potential risk. This process is necessary in order to avoid additional impacts to unimpacted areas. These areas can then be classified as sensitive or relatively resistant. A sensitive area might include a salt marsh system whereas a resistant area would include a jetty or high-energy rock cobble beach. By identifying these areas and their relative sensitivities, the investigator is initiating the process of developing assessment endpoints.

In addition to establishing which areas may be at risk, it is also important to identify the areas in a spill or release that have already been affected by the contaminant. In evaluating these areas through the development of assessment endpoints, the investigator can determine if these areas warrant cleanup or remediation and can assess whether the cleanup is effective.

Therefore, through the process of developing assessment endpoints, the investigator will evaluate habitats that have not been impacted as well as affected habitat areas, and determine assessment endpoints that will be used to determine the ecological function of those areas and whether it is necessary to implement protective measures or remediation to ensure the protection of those habitats.

Through OPA, assessment endpoints have been defined in many coastal areas in the form of maps to determine the location of sensitive areas of special ecological concern. These areas represent assessment endpoints. This aspect of the process helps prepare for a spill or release by providing initial response personnel with critical information on the location of areas that should be protected. This level of information does not formally exist for many inland areas, so development of assessment endpoints for these parts of the country must be conducted on a site-specific basis.

Testable hypotheses are specific risk questions that are based on the assessment endpoints. Based on the mechanism of contaminant toxicity, the number of exposure pathways that may exist for an assessment endpoint, or other factors, there may be more than one question for each assessment endpoint. These questions must be answered and statistically evaluated to reach conclusions relative to the assessment endpoints.

The conceptual model links the contaminants with the sensitive habitats that have been identified through establishing the assessment endpoints. The conceptual model follows the contaminants (stressor) in the environment through ecological (biological) compartments. In the case of a spill, the conceptual model determines the linkage between air, water, sediment, and soil to the receptor of concern, an organism or its habitat. For example, if the contaminant of concern is present in the water, the conceptual model further identifies whether the contaminant is dispersed within the water column, floating along the surface or incorporated into the sediments. This in turn, determines whether the habitats affected will include the benthos, intertidal zone, or water column organisms. The conceptual model ensures that the field study design is appropriate for the compartment affected by the spill or release.

Measurement endpoints are ecological characteristics that are related to the valued characteristics selected as assessment endpoints. They should be linked to the assessment endpoints by the mechanism of toxicity (to the assessment endpoint) and the route of exposure. Measurement endpoints are used to derive a quantitative estimate of potential effects and form a basis for extrapolation to the assessment endpoints. Measurement endpoints should be selected on the basis of potential presence of receptors at the spill or release, the potential for exposure to contaminants based on complete exposure pathways, and sensitivity of the receptor to the contaminants of concern. The availability of appropriate toxicity information on which risk estimates can be based is an important consideration. Endpoints are selected to be representative of exposure pathways and to allow establishment of a causal link between the exposure and the effects.

9.6. NEXT STEPS

9.6.1. Ecological Risk Assessment Needs

- Standardize the ecological risk assessment methodology as applied to spills.

- Assess the process used to determine incidental media ingestion.

9.6.2. Contingency Planning

According to the NCP (Section 300.210 c3v4i), area contingency planning consists of coordination and consultation among individuals, agencies and businesses that could potentially be responsible for an accidental release, the U.S. Fish and Wildlife Service, NOAA, and other interested natural resource management agencies. Area contingency plans should provide for coordinated immediate and effective protection, rescue, and rehabilitation and minimization of risk of injury to fish and wildlife resources and habitats. Protection is extended to marine and freshwater species as well as terrestrial wildlife and includes their habitats and food resources, whether directly or indirectly affected. This information is utilized in the preparation of the area contingency plans, which contain valuable information relative to ecological risk. Although the format and presentation of the risk information is different from what may traditionally be used in formal ecological risk assessment, many of the elements of problem formulation are present in contingency plans. Thus, reevaluation and updates of area contingency plans to utilize a more structured ecological risk process are recommended.

9.6.3. Research on Cleanup Methods

Engineering expertise should be applied to develop new equipment and methods for safely and effectively removing oil and other chemicals from transportation vessels. This will reduce the continuing release of material at the scene of an accident.

The use of dispersants at the scene of oil spills continues to be controversial, and there is no consistent policy among Federal agencies as to where, when, or if they should be used. Dispersants do not remove oil but retard the recoalescence of droplets into slicks, and thus make it appear that less oil is present. The compounds are proprietary, and basic effects data needed for risk assessment are not available. Their ecological impacts are largely unknown, and further research is needed before policy decisions can be made.

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10. GLOSSARY (Adapted in part from U.S. EPA, 1996)

adverse ecological effects—Changes that alter valued structural or functional attributes of ecological entities defined in assessment endpoints. An evaluation of adversity may include a consideration of the type, intensity, and scale of the effect as well as the potential for recovery. While risk assessors evaluate adversity, risk managers determine the acceptability of adverse effects.

assessment endpoint—An explicit expression of the environmental value that is to be protected. An assessment endpoint includes both an ecological entity and specific attributes of that entity. For example, salmon are a valued ecological entity; reproduction and population maintenance of salmon form an assessment endpoint.

biological stressor—As used in this report, synonymous with nonindigenous species - a species introduced (intentionally or unintentionally) beyond its natural range or natural zone of potential dispersal. Biological stressors may also include genetically engineered organisms.

characterization of ecological effects—A portion of the analysis phase of ecological risk assessment that evaluates the ability of a stressor to cause adverse effects under a particular set of circumstances.

characterization of exposure—A portion of the analysis phase of ecological risk assessment that evaluates the interaction of the stressor with one or more ecological entities. Exposure can be expressed as co-occurrence or contact, depending on the stressor and ecological component involved.

conceptual model—The conceptual model describes a series of working hypotheses of how the stressor might affect ecological entities. The conceptual model also describes the ecosystem potentially at risk, the relationship between measures of effect and assessment endpoints, and exposure scenarios.

ecological entity—A general term that may refer to a species, a group of species, an ecosystem function or characteristic, or a specific habitat. An ecological entity can be one component of an assessment endpoint.

ecological risk assessment—The process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors.

ecosystem—The biotic community and abiotic environment within a specified location in space and time.

ecosystem management—Management driven by explicit goals; executed by policies, protocols, and practices; and made adaptable by monitoring and research based on our best understanding of ecological interactions and processes necessary to sustain ecosystem composition, structure, and function (Christensen et al. [1996] ref. in Ch. 8).

exposure—The contact or co-occurrence of a stressor with a receptor.

exposure profile—The product of characterization of exposure in the analysis phase of ecological risk assessment. The exposure profile summarizes the magnitude and spatial and temporal patterns of exposure for the scenarios described in the conceptual model.

exposure scenario—A set of assumptions concerning how an exposure may take place, including assumptions about the exposure setting, stressor characteristics, and activities that may lead to exposure.

hazard—As used in this report, hazard refers to the potential adverse ecological effects of a stressor.

hazard quotient—A ratio of the predicted or estimated levels of a stressor divided by a predicted or estimated level of the stressor causing a specific effect, e.g., for a chemical, the estimated environmental concentration divided by the median lethal concentration.

secondary effects—An effect in which the stressoror acts on supporting components of the ecosystem, which in turn have an effect on the ecological component of interest.

lines of evidence—Information derived from different sources or by different techniques that can be used to interpret and compare risk estimates. While this term is similar to the term "weight of evidence," it does not necessarily imply assignment of quantitative weightings to information.

lowest observed adverse effect level (LOAEL)—The lowest level of a stressor evaluated in a test that causes statistically significant differences from the controls.

measure of ecosystem and receptor characteristics—A measurable characteristic of the ecosystem or receptor that is used in support of exposure or effects analysis.

measure of effect—A measurable ecological characteristic that is related to the valued characteristic chosen as the assessment endpoint.

measure of exposure—A measurable stressor characteristic that is used to help quantify exposure.

measurement endpoint—See "measure of effect."

median lethal concentration (LC_{50})—A statistically or graphically estimated concentration that is expected to be lethal to 50% of a group of organisms under specified conditions (ASTM, 1990).

nonindigenous species—the condition of a species being beyond its natural range or natural zone of potential dispersal; includes all domesticated and feral species and all hybrids except for naturally occurring crosses between indigenous species (OTA, 1993).

no observed adverse effect level (NOAEL)—The highest level of a stressor evaluated in a test that does not cause statistically significant differences from the controls.

primary effect—An effect in which the stressor acts on the ecological component of interest itself, not through effects on other components of the ecosystem (synonymous with direct effect; compare with definition for secondary effect).

problem formulation—The initial stage of an ecological risk assessment where the purpose of the assessment is articulated, assessment endpoints and a conceptual model are developed, and a plan for analyzing and characterizing risk is determined.

receptor—The ecological entity exposed to the stressor.

recovery—The rate and extent of return of a population or community to a condition that existed before the introduction of a stressor. Because of the dynamic nature of ecological systems, the attributes of a "recovered" system must be carefully defined.

risk analysis—The process that includes both risk assessment and risk management.

risk assessor—An individual or team with the appropriate training or range of expertise necessary to conduct a risk assessment (SETAC, 1997)

risk characterization—A phase of ecological risk assessment that integrates the exposure and stressor response profiles to evaluate the likelihood of adverse ecological effects associated with exposure to a stressor. The adversity of effects is discussed, including consideration of the nature and intensity of the effects, the spatial and temporal scales, and the potential for recovery.

risk manager—An individual, team, or organization who can make decisions or take action concerning alternatives for addressing risks. In some situations, risk managers may include a wide range of interested parties or "stakeholders." (Adapted from SETAC, 1997)

risk mitigation—Actions taken to reduce or eliminate exposure to or effects of stressors.

risk quotient—See "hazard quotient."

secondary effect—An effect in which the stressor acts on supporting components of the ecosystem, which in turn have an effect on the ecological component of interest (synonymous with indirect effects; compare with definition for primary effect).

source—An entity or action that releases to the environment or imposes on the environment a chemical, physical, or biological stressor or stressors.

stressor—Any physical, chemical, or biological entity that can induce an adverse response (synonymous with agent).

stressor-response profile—The product of characterization of ecological effects in the analysis phase of ecological risk assessment. The stressor-response profile summarizes the data on the effects of a stressor and the relationship of the data to the assessment endpoint.

uncertainty—"A lack of confidence in the prediction of a risk assessment that may result from natural variability in natural processes, imperfect or incomplete knowledge, or errors in conducting an assessment." (SETAC, 1997)

weight of evidence—See "lines of evidence."

Abstract

The report entitled *"Ecological Risk Assessment in the Federal Government"* was prepared by an interagency work group under the auspices of the Committee on Environment and Natural Resources (CENR). The objective of the work group was to write a document on the major uses of ecological risk assessment by Federal agencies. Eight task groups were formed with a total of 32 scientists from 9 Federal agencies. The task groups addressed eight topics: the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Toxic Substances Control Act (TSCA), the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), nonindigenous species, ecological assessments in ecosystem management, agricultural ecosystems, the endangered/threatened species, and oil spills (accidental releases). The task groups provided examples of current ecological risk assessment areas (established uses), potential uses where components of ecological risk assessment are used, and related ecological assessments and other scientific evaluations that might benefit from the use of ecological risk assessment methodologies. Recommendations were made to improve the science, enhance information transfer, and improve risk management coordination.

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